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FEDERAL REGISTER

Vol. 89 Tuesday,

No. 49 March 12, 2024

Pages 17693–18338

OFFICE OF THE FEDERAL REGISTER

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 126

[Docket No. DHS–2022–0039]

RIN 1601–AB09

Procedures of the Transportation Security Oversight Board Review Panel Concerning Federal Aviation Administration Airman Certificates

AGENCY: Office of the Secretary, DHS

ACTION: Final rule.

SUMMARY: In this final rule, DHS codifies in final form the procedures that apply to appeals before the Transportation Security Oversight Board concerning Federal Aviation Administration Airmen Certificates. The final rule addresses comments stakeholders submitted in response to an interim final rule DHS published on August 9, 2022, on the same topic. DHS amends the IFR rule text to permit parties to consent to electronic service of documents, include a definition of the standard of review that applies to the proceedings, and provide a process to seek remand for good cause shown.

DATES: This rule is effective May 13, 2024.

FOR FURTHER INFORMATION CONTACT: Randall Kaplan, Attorney, Office of the General Counsel, Department of Homeland Security, Washington, DC 20528–0485. Phone: 202 282–9822.

SUPPLEMENTARY INFORMATION:

Abbreviations and Terms Used in This Document

ALJ—Administrative Law Judge
ALPA—Air Line Pilots Association, International
AOPA—Aircraft Owners and Pilots Association
ATSA—The Aviation and Transportation Security Act of 2001
CFR—Code of Federal Regulations
DHS—Department of Homeland Security
FAA—Federal Aviation Administration
FRAP—Federal Rules of Appellate Procedure
Pt.—Part
§—Section
SES—Senior Executive Service
SL—Senior Level
SSI—Sensitive Security Information
Stat.—United States Statutes at Large
Subt.—Subtitle
TSA—Transportation Security Administration
TSOB—Transportation Security Oversight Board
U.S.C.—United States Code

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I. Background and Purpose

A. Statutory History

Section 601(a) of the Vision 100—Century of Aviation Reauthorization Act (Vision 100 Act), Public Law 108–176, 117 Stat. 2490, 2561 (Dec. 12, 2003) (codified at 49 U.S.C. 46111(a)) requires the FAA Administrator to issue an order amending, modifying, suspending, or revoking all or part of an FAA certificate issued under title 49 of the U.S. Code when notified by the Administrator of the TSA that the certificate holder poses, or is suspected of posing, a risk of air piracy or terrorism or a threat to airline or passenger safety. The FAA Administrator may also hold in abeyance or deny an application for a certificate based on a Determination of Security threat, in accordance with 14 CFR 3.205. Following the FAA's issuance of such an order, abeyance, or denial, an adversely affected U.S. citizen may challenge the TSA's determination that they pose or are suspected of posing such a risk (called a Determination of Security Threat) at a hearing on the record before an ALJ. 49 U.S.C. 46111(b)–(c). Any party to the proceedings before the ALJ may appeal the ALJ's decision to a Review Panel appointed by the TSOB. 49 U.S.C. 46111(d). Any person who is substantially affected by the TSOB Review Panel's action may seek review by an appropriate U.S. Court of Appeals. 49 U.S.C. 46110(a) and 46111(e). The TSA Administrator may seek such review if it is determined that the Review Panel's action will have a significant adverse impact on carrying out 49 U.S.C. Subt. VII, Pt. A, which establishes Federal programs to ensure safety in aviation and air commerce.

Section 102(a) of the Aviation and Transportation Security Act of 2001 (ATSA), Public Law 107–71, 115 Stat. 597, 604 (Nov. 19, 2001) (codified at 49 U.S.C. 115) established the TSOB. The Secretary of Homeland Security, or the Secretary's designee, serves as the Chairperson of the TSOB. 49 U.S.C. 115(b)(2). The other statutory members of the TSOB are the Secretaries of Transportation, Defense, and the Treasury, the Attorney General, the Director of National Intelligence, or their designees, and one individual appointed by the President to represent the National Security Council. 49 U.S.C. 115(b)(1).

When the TSOB receives an appeal from an ALJ's decision regarding a TSA Determination of Security Threat, it must establish a Review Panel to review the decision. 49 U.S.C. 46111(d). The members of the Review Panel may not be TSA employees, and they must hold an appropriate security clearance. 49 U.S.C. 46111(d)(1) and (2). A TSOB Review Panel may affirm, modify, or reverse the ALJ's decision. 49 U.S.C. 46111(d)(3).

B. TSA Vetting Process and Redress for Determinations of Security Threat

Following the terrorist attacks of September 11, 2001, Congress recognized the need for an entirely new and comprehensive regulatory regime focused on securing the transportation system. Congress enacted many laws requiring TSA to conduct security threat assessments (STAs) of individuals who perform security functions in or have access to the transportation system. At present, TSA conducts STAs for more than 28 million individuals every day. The vetted populations include airport workers, airline employees, air cargo handlers, FAA certificate holders, individuals seeking airspace waivers, drivers hauling hazardous materials in commerce, merchant mariners and

longshoremen working in ports and on vessels, trusted travelers, flight students, chemical facility employees, and others. In accordance with governing statutes and fundamental principles of due process, TSA developed these vetting programs to collect ample biographic information to verify the identity of the applicant, conduct informed evaluations of the vetting results, and provide robust redress to protect against incorrectly designating an individual as a threat to national or transportation security, or of terrorism.

Of the approximately 30 million individuals TSA vets daily, over 5 million hold FAA certificates. To conduct this vetting, TSA uses the biographic information the FAA collects from applicants and certificate holders and compares it against several intelligence and law enforcement databases. As part of this vetting, TSA is required to ensure that individuals ''are screened against all appropriate records in the consolidated and integrated terrorist watchlist maintained by the Federal Government before being certificated'' by the FAA.[1] TSA's intelligence analysts review any derogatory information generated during the vetting to determine whether the individual poses or is suspected of posing a security threat. If TSA believes the individual poses, or is suspected of posing, a security threat, TSA issues a Determination of Security Threat, notifies the FAA of the Determination of Security Threat, and asks the FAA to amend, modify, suspend, or revoke the individual's certificates. Once the FAA takes action, the individual, if a U.S. citizen, may appeal the Determination of Security Threat underlying FAA's action to an ALJ.

The ALJs who hear these appeals are experienced judges who are frequently called upon to review TSA's eligibility determinations for other transportation worker populations and who possess the appropriate security clearance to review classified or otherwise protected information and evidence. The ALJs receive and assess information and evidence; hold and regulate the course of hearings; dispose of procedural motions; and examine witnesses. The ALJ conducts a *de novo* hearing, reviews the evidence and testimony presented (including the information on which TSA based its Determination of Security Threat), and issues a decision based on that review. Either party may appeal the ALJ's decision to the TSOB Review Panel.

[1] 49 U.S.C. 44903(j)(2)(D)(i).

C. TSOB Review Panel Procedures for FAA Certificate Appeals

Following the first FAA certificate appeal to the TSOB Review Panel in 2010, the TSOB Chairperson issued procedures in May 2011 for use in all such appeals. DHS provided these written procedures directly to litigants when they file an appeal of the ALJ's decision. All of the 2011 procedures governing briefs and motions, the conduct of proceedings, the treatment of sensitive documents, and the standard of review were closely aligned with the Federal Rules of Appellate Procedure (FRAP) and administrative practice procedures. The 2011 procedures ensured that parties have adequate time to seek review, prepare briefs, respond to opposing party assertions, request extensions of time, and request hearings. The 2011 procedures established the standard of review, substantial evidence on the record, for the Review Panel to apply when reviewing evidence and reaching a decision.

D. Summary of the IFR

DHS determined it would be best to codify the appeal procedures to provide full transparency and consistency of process for all potential litigants and Review Panel members, and published the IFR in August 2022.[2] DHS based this decision on the likelihood of increasing numbers of appeals and to ensure all TSOB Review Panels apply consistent standards and procedures.[3]

Requests for review of Determinations of Security Threat are on the rise. From 2011 to November 30, 2021, the TSOB received only one additional appeal, which was resolved by decision of the TSOB Review Panel on September 23, 2021. However, currently there are four Determinations of Security Threat regarding U.S. citizens pending review by an ALJ, and an additional six U.S. citizens have timely initiated the redress process in response to a Determination of Security Threat. Overall, TSA's caseload with respect to Determinations of Security Threat increased by over 100% between Fiscal Year 2019 and Fiscal Year 2022, in significant part due to rising investigations of domestic terrorism-related cases in which affected certificate holders may seek review of Determinations of Security Threat by an ALJ and then the TSOB. Given this trend, codifying the procedures helps ensure optimal transparency in the process for affected individuals, clear understanding of the procedures, and consistency in the application of the standards and procedures.

Under the Administrative Procedure Act (APA), rules involving ''agency organization, procedure, or practice'' like the TSOB Review Panel procedures, do not require advance notice and the opportunity to comment before becoming final.[4] The IFR was procedural within the meaning of the APA because it merely codified current practice and did not alter the rights of or substantive standards applied to an individual appearing before the TSOB Review Panel, such as whether the individual poses or is suspected of posing a threat. Nevertheless, DHS agrees with the views of the Administrative Conference of the United States (ACUS) that public comment serves a critical role in the development of sound policy, and that agencies should solicit comment when it is possible to do so.[5] Consequently, DHS requested comments on the IFR from the public.

The IFR generally codified the written 2011 TSOB Review Panel procedures with certain updates and clarifications where necessary for full transparency. The rule addressed appeals to the TSOB Review Panel from an ALJ's decision concerning TSA's Determination of Security Threat and did not apply to other matters that the TSOB oversees. The IFR established requirements for TSOB Review Panel members and the docket clerk; the standard of review applicable to appeals; timelines for appeals and responses; filing and supplementing the record; entry of appearance; motions, briefs, and the administration of hearings; procedures for the use of classified materials, sensitive security information, and other protected information; and the effect of the TSOB Review Panel action.[6]

II. Response to Comments on the IFR

DHS received comments on the IFR from two organizations: the Air Line Pilots Association, International (ALPA) and the Aircraft Owners and Pilots Association (AOPA). ALPA represents the safety and security interests of over 66,000 professional airline pilots flying

[2] *See* Procedures of the Transportation Security Oversight Board Review Panel Concerning Federal Aviation Administration Airman Certificates, 87 FR 48431 (August 9, 2022).

[3] In 2021, the TSOB Review Panel chose to apply a *de novo* standard of review rather than the substantial evidence standard required in the appeal procedures.

[4] *See* 5 U.S.C. 553 (b)(A). *See also* 87 FR 48431, 48436–37 for a full discussion of the use of procedural rules.

[5] *See* ACUS Recommendation 92–1, The Procedural and Practice Rule Exemption from the APA Notice-and-Comment Rulemaking Requirements, (December 18, 1992).

[6] *See* 87 FR 48431, 48433–36 for an explanation of the IFR rule text.

for 41 airlines in the United States and Canada. AOPA represents 300,000 members who operate 85% of all general aviation aircraft operating in the United States. Over 72,000 members of AOPA participate in AOPA's Pilot Protection Services, which provides legal services to individuals who are subject to FAA and TSA enforcement actions. The comments relate to some general matters and several specific topics, including the use of electronically/electronic service for service of documents; standard of review the TSOB Review Panel applies; process for non-governmental counsel to have access to protected information; precedential nature of TSOB Review Panel decisions; publication of TSOB Review Panel decisions; and the treatment of constitutional issues.

A. General Matters

ALPA suggested that DHS include in this response to comments a full discussion of the procedures that currently apply to the appeal of an FAA certificate holder to an ALJ following revocation, suspension, or modification of the certificate. TSA provides each affected certificate holder actual notice of those procedures by letter when the certificate action is taken by the FAA. Also, TSA is in the process of amending its regulations to codify those procedures in 49 CFR part 1540. Because this rule concerns procedures applicable to an appeal to a TSOB Review Panel, we believe a full discussion of the current appeal process to an ALJ in this document is unnecessary and may be confusing to the public.

AOPA encourages DHS to periodically reexamine and update these regulations. For any future amendments to these rules, AOPA also encourages DHS to continue its practice of seeking public comment on procedural rules. DHS and its components periodically review all regulations in accordance with Executive Orders [7] and sound regulatory policy. This review may result in changes to existing rules, the development of new standards, or terminating standards that are no longer necessary. DHS will follow that same process with this rulemaking and revise the language as necessary.

B. Use of Electronic Service of Documents

AOPA supports filing and serving documents electronically, as permitted by § 126.13 of this rule, and suggests that the rule also address how to consent to electronic service, how to establish evidence of electronic service, and how to compute time when documents are filed or served electronically. Also, AOPA recommends that the rule establish a presumption of consent to future electronic service when a document is transmitted electronically and there is evidence to confirm its successful transmission. AOPA encourages the TSOB Review Panel to consider providing automated receipts in response to electronic filings made to the TSOB Docket Clerk. AOPA suggests adding the following language to § 126.13(b): 'A party may consent to service via electronically/electronic service by filing a document expressly stating such a preference with the TSOB Docket Clerk and serving a copy on all other parties.' AOPA asks DHS to adopt language from the Federal Rule of Appellate Procedure (FRAP) 26, Computing and Extending Time, for use in the procedures before the TSOB Review Panel.

DHS Response: DHS agrees with adding the suggested language to § 126.13(b) to provide a method by which parties may consent to service of documents electronically. Therefore, we have revised the text in § 126.13(b) to state that a party may consent to electronic service by filing a document that expressly states such a preference with the TSOB Docket Clerk, and serving a copy on all other parties.

DHS is not inclined at this time to establish a presumption of consent to future electronic service when a document is transmitted electronically and there is evidence to confirm its successful transmission. To the extent we have individuals who initiate an appeal without counsel and use electronic means to do so, they may have no knowledge of the presumption this establishes for future service of documents. Generally, parties should knowingly and affirmatively consent to changes in service, not by presumption. Moreover, the new language in § 126.13(b) creates a simple process by which individuals may elect to establish a presumption of consent to future electronic service at any time.

DHS is not inclined to revise the rule text identifying the filing date and computation of time for documents filed through electronically/electronic service. The existing rule text in § 126.13(c) establishes that service of all documents, regardless of transmittal method, occurs on the date on which the TSOB Docket Clerk receives the document. We believe the Docket Clerk is in the best position to determine whether it is necessary to set up automated electronic receipts for documents filed through electronically/electronic service or whether another kind of action is preferable.

We believe adopting the FRAP Rule 26 for TSOB Review Panel proceedings is not advisable at this time. Rule 26 defines terms used in the text of the FRAP on time computation, including *next day, last day,* and *legal holiday.* These terms are not used in the TSOB Review Panel rulemaking, and thus, there is no need to define them. Also, the FRAP Rule 26 explains that Saturdays, Sundays, and legal holidays must be counted when computing timelines. We believe there is no need to add this language because the TSOB Review Panel rule does not suggest or provide exceptions for these days when computing time. The FRAP Rule 26 provides procedures that apply when the Clerk's Office is inaccessible; given the extensive use of electronically/electronic service for service of documents today, we believe there is little need to provide for circumstances when the ''Clerk's Office'' is inaccessible for TSOB Review Panel proceedings. The TSOB Review Panel does not rely on a typical ''Clerk's Office'' that has a stationary presence in courthouses and handles a high volume of judicial proceedings. Rather, the rule establishes that an individual from within the DHS Office of the General Counsel serves as the TSOB Docket Clerk, available to receive documents electronically at virtually any time. For all of these reasons, we believe the TSOB Review Panel rule text is sufficiently clear on the computation of time and changes are unnecessary.

C. Standard of Review

Section 126.9(a) establishes that the standard of review the TSOB Review Panel applies is substantial evidence, and in paragraph (b) states that the Review Panel will not consider the constitutionality of any statute, regulation, Executive Order, or order issued by TSA. Both ALPA and AOPA commented on this section. AOPA seeks confirmation that while the TSOB Review Panel gives deference to an ALJ's factual findings supported by substantial evidence in the record, the Review Panel reviews legal determinations made by the ALJ using the *de novo* standard of review. Also,

[7] *See* Exec. Order No. 13610, 77 FR 28467 (May 10, 2012); Exec. Order No. 13563, 76 FR 3821 (Jan. 18, 2011); *see also,* Periodic Retrospective Review, 86 FR 36075 (Jul. 8, 2021); Learning from Regulatory Experience, 82 FR 61738 (Dec. 29, 2017); Retrospective Review of Agency Rules, 79 FR 75114 (Dec. 17, 2014); Review of Existing Agency Regulations, 60 FR 43108 (Aug. 18, 1995).

AOPA suggests that DHS either remove § 126.9(b) or amend it to include a statement that parties must raise constitutional issues at the agency level to preserve them for judicial review.

ALPA states that the substantial evidence standard of review is not indicated or required by 49 U.S.C. 46111(d). ALPA asserts that this standard of review is too restrictive to provide adequate procedural and substantive right protections. Also, ALPA suggests that because the rule does not include a definition of substantial evidence, it is open to interpretation by each TSOB Review Panel. ALPA asserts that DHS should amend § 126.9 to follow or incorporate the standard of review the National Transportation Safety Board (NTSB) uses in its Rules of Practice in Air Safety Proceedings, codified at 49 CFR 821.49. Those procedures apply to the NTSB review of ALJ decisions that affirm, modify, amend, or reverse FAA Certificate actions related to safety issues. The NTSB procedures permit the Board to consider if the ''findings of fact are supported by a preponderance of reliable, probative, and substantial evidence.''

DHS Response: DHS is adding a definition of the term ''substantial evidence'' to the rule to make certain there is no room for confusion or interpretation as to what the standard means. It is a term that is widely used and generally not subject to varying interpretations, but a definition of it in the rule text provides optimum clarity for all parties associated with TSOB Review Panel proceedings. The definition is ''substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'' This is the standard of review that is applied in administrative review proceedings like those of the TSOB Review Panel.

In practical terms, the substantial evidence standard is more deferential to the decision below than the preponderance of the evidence standard of review. A preponderance of the evidence means there is a greater than 50% chance an assertion or decision is true, and typically applies to civil court cases. The substantial evidence standard does not require a reviewing body to find that the decision below is more likely than not to be true, but that the decision is reasonable given all of the information presented. The NTSB procedural rule that ALPA urges DHS to use for this rule requires the Board to find that the ALJ's findings of fact are supported by ''a preponderance of reliable, probative, and substantial evidence,'' which is a hybrid standard that combines preponderance of the evidence with substantial evidence and probative evidence.

DHS does not wish to apply the NTSB standard to TSOB Review Panel cases. DHS agrees with ALPA's statement that 49 U.S.C. 46111(d) does not reference or require the substantial evidence standard of review for TSOB Review Panel proceedings. However, use of the substantial evidence standard for appellate review of administrative proceedings at the Federal level is commonplace.[8] The use of this standard for reviewing an ALJ's decision recognizes the significant expertise ALJs bring to the Federal administrative process. ALJs handle a variety of subject matters, legal issues, motions, witness testimony, statutory and regulatory interpretation, and matters advanced by *pro se* appellants as well as those represented by counsel. Most ALJs have very active dockets that require sound and timely decision-making. To require a reviewing body like the TSOB Review Panel to use the less deferential *de novo* standard for reviewing ALJ proceedings would increase the time and resources needed to resolve appeals, with scant justification that is it necessary. Congress and agencies would not authorize the use of the substantial evidence standard of review so widely if evidence existed demonstrating that proceedings before ALJs were insufficient or wrought with problems.

In addition to the factors discussed above, it is important to note that § 126.7 of the current IFR authorizes the TSOB Review Panel to remand a matter to the ALJ to ''address particular issues or consider additional testimony or evidence.'' Thus, if the TSOB Review Panel has concerns about the outcome reached at the ALJ level or cannot reach a decision on appeal, it can send the matter back to the ALJ with instructions on examining issues and obtaining additional testimony or evidence. This section enables the TSOB Review Panel to seek correction or clarification of issues that are vague, questionable, or unsupported by the record, and essentially to correct the kind of procedural and substantive shortcomings ALPA expressed concern about in its comments. Also, ALPA suggests DHS amend § 126.19 to permit the TSOB Review Panel to remand the case to the ALJ for additional proceedings upon motion of the parties and ''a showing of good cause.'' DHS sees value in this suggested revision to the IFR and is adding this language as new § 126.19(b)(3). This addition to the rule text further minimizes the need to require a higher standard of review such as a preponderance of the evidence or the hybrid standard the NTSB uses in its appellate procedures.

D. Review of ALJ Legal Determinations and Objections to Prejudicial Errors

Both ALPA and AOPA submitted comments asserting that an ALJ's legal determinations and prejudicial errors of law and procedure should receive special treatment by the TSOB Review Panel. AOPA seeks confirmation that while the TSOB Review Panel gives deference to an ALJ's factual findings based on substantial evidence in the record, the Review Panel applies *de novo* review to any legal determinations the ALJ makes. ALPA asserts that § 126.23(a)(2) should be revised to state that a party's objections to an ALJ's prejudicial errors of the law or procedure are reviewable by the TSOB Review Panel.

DHS Response: DHS confirms that appellate courts and administrative review panels such as the TSOB Review Panel apply the substantial evidence standard to factual issues, but apply essentially a *de novo* review of legal determinations an ALJ makes. Reviewing panels and courts retain the authority to review and determine purely legal questions to determine if they are erroneous as a matter of law when raised on appeal, without deference to the lower court. In FAA certificate holder cases appealed to the TSOB Review Panel, the sustainability of the underlying security threat determination is based on a factual determination, subject to the substantial evidence standard of review.

DHS is not inclined to revise § 126.23(a)(2) to state that a party's objections to an ALJ's prejudicial errors of law or procedure are reviewable by the TSOB Review Panel because it is unnecessary. The current language in § 126.23(a)(2) states the appellant must ''enumerate the appellant's objections to the ALJ's decision'' in the appellant's brief perfecting the appeal. This language is broad and permits the

[8] *See, e.g.,* 29 CFR 24.110(b), which mandates the use of the substantial evidence standard by the Department of Labor Administrative Review Board (ARB) when reviewing an ALJ decision. *See also, Stone & Webster Constr., Inc.* v. *U.S. Dep't of Labor,* 684 F.3d 1127, 1132 (11th Cir. 2012), in which the court details the effect of the standard's codification on later appeals (''As a result, we now show less deference to an ARB that disturbs the factual findings of an ALJ.''); 33 U.S.C. 921(b)(3) and 20 CFR 802.301(a), Department of Labor Benefits Review Board; 42 CFR 3.548(h), Department of Health and Human Services Departmental Appeals Board; 32 CFR 200.2021(h), Defense Health Agency; 42 U.S.C. 405(g), Social Security Administration; 12 U.S.C. 1848, Federal Reserve Board; 49 CFR 386.67(b), Federal Motor Carrier Safety Administration.

appellant to raise perceived prejudicial errors of law or procedure in the appeal.

E. Access to Protected Information

AOPA and ALPA commented on the need for the appellant and counsel to have access to protected information during the TSOB Review Panel proceeding. Both organizations recommend DHS create a process for non-government counsel representing non-government parties in TSOB Review Panel actions to request designation as having a ''need to know,'' be appropriately vetted, and once designated, have access to classified and other protected information, and SSI.

The IFR rule text in § 126.17 addresses procedures for the use of classified, sensitive security, and other protected information. The rule defines ''other protected information'' as information the government is authorized to withhold under statute, regulation, or Executive Order. Paragraph (b) in § 126.17 prohibits the TSOB Review Panel from disclosing classified or other protected information to a non-government party or counsel, and prohibits disclosing SSI to those individuals unless TSA determines the party had a preexisting need to know specific SSI as a covered person under 49 CFR 1520.7 and 1520.11.

DHS Response: DHS believes it is inadvisable to establish a process for non-government individuals to have access to classified or other protected information during TSOB Review Panel proceedings. There is longstanding precedent on the need for strict controls over classified and protected information, and we do not find sufficient justification here to alter those policies and procedures. We believe unintended and serious consequences may occur as the circle of individuals with access to this information grows, particularly where there is very little ability to track or prevent additional sharing of the information. However, in accordance with the SSI regulations codified at 49 CFR part 1520, appellants and their counsel may have access to SSI that is associated with their TSOB Review Panel case. In other words, § 126.17(b) neither expands nor contracts a party's authorization to receive SSI in accordance with 49 CFR part 1520.

E. Publication and Precedential Nature of Decisions

AOPA recommends that DHS revise § 126.27 to include a method for publishing TSOB Review Panel decisions in such a way as to protect an affected individual's identity. Also, AOPA recommends DHS revise § 126.29(b) to state that TSOB Review Panel actions are precedential for future ALJ decisions and TSOB Review Panel actions. AOPA asserts that providing precedential value to TSOB Review Panel decisions will bring greater consistency and efficiency to the process, and assist potential appellants in making litigation decisions.

DHS Response: DHS does not believe it is advisable or necessary to publish decisions or amend the rule to state that the decisions serve as precedent for future ALJ and TSOB cases. The number of cases is very low and the fact patterns so unique that it is difficult to see how one case could be precedential for another. Also, as security threats evolve over time, the factors that contribute to determining whether an individual poses a security threat may also evolve. Attaching precedential authority to older decisions may result in improper or incongruous results. Since DHS is not inclined to publish decisions at this point in time, it is not necessary to address AOPA's recommendation for a process to protect the identity of an affected party when publishing a decision.

F. Challenging TSOB Panel Membership

AOPA recommends that DHS provide a mechanism for a party to file a motion to disqualify a TSOB Review Panel member due to conflict of interest concerns.

DHS Response: DHS does not believe there is sufficient justification for this recommendation. There are checks in the TSOB appointment process that minimize the risk that a Panel member would have a conflict of interest concerning a specific case. Panel members must be a member of the Senior Executive Service or a Senior Level employee, which typically means the individual has a longstanding career in the government and is subject to strict standards of ethics. Panel members also may not be employed by the FAA or TSA. These two requirements minimize the chance that a Panel member has a conflict related to a specific FAA certificate revocation or suspension.

G. Add Court of Appeals Filing Deadline

ALPA recommends that DHS revise § 126.29 to include the Court of Appeals filing deadline, which is 60 days from the date the TSOB Review Panel issues its decision, under 49 U.S.C. 46110.

DHS Response: DHS is amending § 126.29 to state that an appeal of the TSOB Review Panel must be done in accordance with the requirements of 49 U.S.C. 46110, which allows for 60 days. This provides litigants with the information necessary to ensure timely appeals, and if the statute changes in the future, there would be no need to also amend this regulation.

H. Constitutional Issues

AOPA recommends that DHS remove paragraph 126.9(b) or revise it to state that constitutional issues must be raised before the agency in order to be preserved for judicial review.

DHS Response: DHS is not inclined to remove or revise paragraph (b). The language states that a TSOB Review Panel will not review the constitutionality of any statute, regulation, Executive Order, or order issued by TSA. This sufficiently puts litigants on notice that constitutional matters do not fall within TSOB Review Panel authority, but we do not believe it necessary to provide litigants information on when or where those issues must be raised outside of the TSOB Review Panel proceedings.

III. Discussion of the Final Rule and Summary of Changes

The language below describes the rule text as it appears in the IFR and where DHS is changing the rule text in response to comments received.

§ 126.1 Purpose and Scope

Section 126.1 describes the general purpose and scope of part 126, which is to establish procedures by which a TSOB Review Panel is appointed and reviews an appeal from an ALJ's decision regarding a TSA Determination of Security Threat. The procedures apply to appeals involving applications for certificates that are denied or held in abeyance as well as orders to amend, modify, suspend or revoke FAA certificates. Congress left to DHS's discretion the development of detailed procedures for TSOB review of an appeal from an ALJ's decision.

§ 126.3 Definitions

Section 126.3 provides definitions of important terms that are used in the rule. The 2011 procedures did not include a definition section, but based on the experience DHS has gained in prior TSOB Review Panel cases and other administrative review programs DHS and its components administer, establishing definitions of key terms aids all parties engaged in the review process. These definitions are taken from existing statutory, regulatory, or Executive Order language, or reflect common usage meanings. DHS is adding a definition of the term ''substantial evidence'' as discussed in II.C. above.

'Classified information' has the same meaning the term has in Executive

Order 13526, *Classified National Security Information,* or its successor Executive Order. The term 'communication technology' means telephone or videoconferencing platform. The term 'Sensitive Security Information' (SSI) is information described in 49 CFR 1520.5. The rule defines 'other protected information' as any other information that the government is authorized by statute, regulation, or Executive Order to withhold. The rule defines 'Transportation Security Oversight Board (TSOB)' as the board established pursuant to 49 U.S.C. 115. Finally, 'Transportation Security Oversight Board (TSOB) Review Panel' is defined as the panel established pursuant to 49 U.S.C. 46111(d) to consider an appeal from a decision of an ALJ as the result of a hearing under 49 U.S.C. 46111(b).

§ 126.5 Appointment of TSOB Review Panel and TSOB Docket Clerk

Section 126.5(a) provides that TSOB members must designate individuals who meet specific criteria to serve in a pool of potential Panel members for a period of two years. The criteria for nominees are listed in paragraphs (a)(1) through (5). The nominee must be a member of the Senior Executive Service (SES) or a Senior Level (SL) employee to ensure that he or she possesses the appropriate level of experience to evaluate the issues and record before the Panel. The nominee must hold the appropriate security clearance to ensure that he or she can effectively review an administrative record that contains classified material. Nominees may not be employees of TSA or FAA, which ensures an unbiased review of TSA's security threat determination. Although 49 U.S.C. 46111(d) excludes only TSA employees from membership on a TSOB Review Panel, the TSOB Chairperson has determined that FAA employees should also be excluded. Exclusion of both TSA and FAA employees from participation in the TSOB Review Panel pool avoids the possible appearance of impartiality or lack of independent review. To the extent practicable, the nominee will have a legal background and be engaged in the practice of law on behalf of the U.S. government. Although these qualifications were not included in the 2011 procedures, through experience in this and other administrative appeal programs, DHS has found that individuals with this background enhance a Review Panel's ability to efficiently and accurately assess the legal arguments the parties assert during the appeal, and to prepare cogent decisions. Finally, to the extent practicable, a nominee will be familiar with transportation security issues. This factor was not included in the 2011 procedures, but DHS has found that such a background enhances the efficiency and accuracy of the review process.

Paragraph (b) provides that TSOB members must designate officials for the TSOB Review Panel when each two-year period expires. Paragraph (c) states that the General Counsel of the Department of Homeland Security, or the General Counsel's designee, will appoint an individual from within the Office of the General Counsel to serve as the TSOB Docket Clerk. The TSOB Docket Clerk serves as the Review Panel's point of contact for the public and the parties to ALJ proceedings. Paragraph (d) states that when the TSOB Docket Clerk receives a properly and timely filed appeal from an ALJ's decision, the TSOB Chairperson will select at least three individuals from the Review Panel pool to serve on a Review Panel to review the ALJ's decision. The TSOB Chairperson has discretion to choose which individuals from the pool will serve on a TSOB Review Panel. In making selections for a TSOB Review Panel, the TSOB Chairperson will, to the extent practicable, select at least one person with a legal background to serve as a Panel Member. A three-member Review Panel allows for appropriate deliberation and the exercise of independent judgment, and is similar to the size of other Federal Government administrative review panels and the panels that hear cases in the U.S. Courts of Appeals.[9]

§ 126.7 Function of TSOB Review Panel

Section 126.7 requires a TSOB Review Panel to review an ALJ's decision and affirm, modify, or reverse that decision, or remand the matter to the ALJ for reconsideration.

§ 126.9 Scope and Standard of Review

Section 126.9(a) states that the standard of review a TSOB Review Panel uses in considering an ALJ's decision is whether the decision is supported by substantial evidence in the record. The term ''standard of review'' refers to the degree of deference a reviewing court gives to the court below. The 2011 procedures stated that the standard of review is whether the ALJ's decision reasonably supports the conclusion that the FAA certificate holder does or does not pose a security threat, which is equivalent to ''substantial evidence in the record.'' Substantial evidence means ''such relevant evidence that a reasonable mind might accept as adequate to support a conclusion.'' [10] In contrast, the ALJ applies a *de novo* standard of review to TSA's Determinations of Security Threat for FAA certificate holders. A ''*de novo*'' standard of review applies the least amount of deference to the court below; the reviewing court examines the evidence as though it is being considered for the first time, allowing the reviewing court to substitute its own judgment about the application of the law to the facts.

Generally, the substantial evidence standard of review is used in civil cases relating to administrative decisions at the Federal level. TSA administers several vetting programs with robust redress processes that, like the TSOB Review Panel procedures, include multiple levels of review. One transportation-related example is the review process for the Transportation Worker Identification Credential (TWIC) and Hazardous Materials Endorsement (HME) programs found at 49 CFR 1515.5 through 1515.11. TWIC and HME applicants undergo an STA that includes criminal, immigration, terrorist, and other database checks. *See* 49 CFR part 1572. If TSA determines a TWIC or HME applicant poses a security threat, TSA issues a written preliminary determination of threat assessment that includes information on how to appeal the assessment to TSA. TSA reviews all documents the applicant provides in the appeal, essentially providing *de novo* review of the case, and issues a final determination based upon its review of all relevant information available to TSA. The applicant may then appeal the final determination to an ALJ, and the ALJ applies the substantial evidence standard of review. An unsuccessful applicant may then appeal the ALJ's decision to the TSA Final Decision Maker, who also applies the substantial evidence standard of review. These regulations, issued through notice-and-comment rulemaking along with the corresponding STA requirements, have been in use for over a decade.

Cases that reach the TSOB Review Panel have undergone multiple levels of review within TSA and have been reviewed by an ALJ. TSA has access to all of the factual and intelligence information generated during the vetting of the FAA certificate holder, and the expertise to evaluate whether the information supports a security threat

[9] *See* 28 U.S.C. 46(b) (providing for three-judge panels to hear and determine cases in the U.S. Courts of Appeals); 49 CFR 1108.6 (providing for a three-member panel of arbitrators for the Surface Transportation Board).

[10] *See Richardson* vs. *Perales,* 402 U.S. 389 (1971).

determination. Then, the ALJ applies a *de novo* standard of review to determine whether TSA correctly applied its standard on whether an individual poses or is suspected of posing a security threat. This *de novo* review includes the review of information and evidence; examining witnesses and weighing the veracity and probity of their testimony; and determining whether a preponderance of the evidence supports the security threat determination. Consequently, the TSOB Review Panel ought to apply the more deferential substantial evidence standard of review, not a *de novo* standard. This standard of review requires the Panel to determine whether a reasonable person might accept the evidence presented as adequate to support the ALJ's conclusion.

The 2011 and 2021 Review Panels relied on the 2011 procedures but applied different standards of review. Codifying procedures in this rule avoids future panels using different standards of review.

Paragraph (b) states that a TSOB Review Panel will not consider the constitutionality of any statute, regulation, Executive Order, or order issued by TSA. A TSOB Review Panel is an administrative body that lacks the authority or expertise to decide constitutional questions.[11] Constitutional claims or questions must be addressed by an appropriate U.S. Court of Appeals reviewing the TSOB Review Panel's action. When making its decisions, the Review Panel considers the entire record of the proceedings before the ALJ. The Review Panel may also consider additional materials that are properly added to the record through a duly filed motion, as permitted in § 126.19(b).

§ 126.11 Counsel

Section 126.11(a) gives all parties to proceedings before a TSOB Review Panel the right to be represented by counsel. Because Review Panel proceedings are civil proceedings that cannot result in a party's incarceration, the Federal Government is not required to provide legal counsel to represent a party who is unable to pay for an attorney. Thus, parties appearing before a TSOB Review Panel must obtain counsel at their own expense. TSA will designate legal counsel from among the attorneys in the DHS Office of the General Counsel who cover TSA's programs and issues on a daily basis, to represent TSA in Review Panel proceedings. This section also states that counsel for TSA must hold a security clearance commensurate with the information in the record on appeal. This requirement was not explicitly listed in the 2011 procedures, but has always been required for TSOB and similar administrative appeal procedures.

Section 126.11(b) provides that the General Counsel of DHS, or the General Counsel's designee, will appoint legal counsel who, in the General Counsel's discretion, has the requisite knowledge and experience to effectively assist a TSOB Review Panel reach a sound decision. The Review Panel's counsel facilitates communication between the Docket Clerk and the Review Panel, and assists with legal research, drafting documents, and similar tasks consistent with typical legal support. Appointed counsel must hold a security clearance that enables access to all materials in the record under review.

§ 126.13 Notice of Appeal and Service

Section 126.13 instructs parties on how to request TSOB review of an ALJ's decision and how to serve notice on all other parties. Any party to proceedings before the ALJ may file a notice of appeal with the TSOB via certified mail or electronically/electronic service. DHS strongly encourages parties to file all documents and consent to service via electronically/electronic service to the TSOB Docket Clerk. Allowing parties to file a notice via electronically/electronic service will expedite the receipt of documents and the review process.

Section 126.13(a) provides that a notice of appeal must be filed within 60 calendar days of the date of issuance of the ALJ's decision. This time limit is drawn from Rule 4 of the FRAP, which generally allows parties to a civil action in U.S. District Court 60 days to file a notice of appeal with an appropriate U.S. Court of Appeals in a case in which the United States or a Federal agency is a party.

Section 126.13(b) provides the addresses for the TSOB Docket Clerk and instructions for filing any document with a TSOB Review Panel. As discussed in II.B above, DHS is adding language to this paragraph to permit litigants to expressly state a preference for service by electronically/electronic service.

Section 126.13(c) specifies the date on which a document is deemed filed. The date of filing is the date that the document is received by the TSOB Docket Clerk.

Section 126.13(d) provides that a TSOB Review Panel generally must reject and summarily dismiss a notice of appeal that is filed after the expiration of the 60-day deadline for appealing an ALJ's decision. The Review Panel, in its discretion, may accept the untimely notice upon a written showing of good cause for failing to meet the deadline.

Section 126.13(e) provides that if a party files a notice of appeal but fails to perfect the appeal by timely filing a supporting brief, a TSOB Review Panel may dismiss the appeal.

Section 126.13(f) explains that if an appeal is dismissed in accordance with paragraph (d) or (e), the ALJ's written decision becomes final. This provision did not appear in the 2011 procedures, but DHS is adding this to ensure all parties understand the practical effect of a dismissal.

§ 126.15 Entry of Appearance

Section 126.15 requires parties and counsel to enter appearances in writing before a TSOB Review Panel within 15 calendar days of being served with a notice of appeal. This requirement was not part of the 2011 procedures, but DHS is adding it to ensure efficiency and timeliness in the review process based on prior experience in TSOB. Also, the requirement to file an entry of appearance is consistent with Rule 12 of the FRAP.

§ 126.17 Procedures for Classified Information, Sensitive Security Information (SSI), and Other Protected Information

Section 126.17 provides the procedures for handling classified information, SSI, and other protected information during proceedings before a TSOB Review Panel. This section did not appear in the 2011 procedures, but the processes outlined here reflect the current practice of the review panels. The procedures are consistent with the statutory provisions regarding the use of classified evidence in hearings pursuant to 49 U.S.C. 46111(g), and the protection of SSI set forth in 49 CFR 1520.9. This section sets deadlines for TSA with respect to protected information to aid efficiency and transparency in the process. Section 126.17(a) provides that TSA must file a notice of protected information within 30 calendar days of filing or being served with a notice of appeal. The notice of protected information must indicate whether the record of proceedings before the ALJ contains classified information or SSI. This notice will alert a TSOB Review Panel to take appropriate steps to

[11] *See Thunder Basin Coal Co.* v. *Reich,* 510 U.S. 200, 215 (1994) (''[W]e agree that adjudication of the constitutionality of congressional enactments has generally been thought beyond the jurisdiction of administrative agencies.''); *Mont. Chapter of Ass'n of Civilian Technicians, Inc.* v. *Young,* 514 F.2d 1165, 1167 (9th Cir. 1975) (''[F]ederal administrative agencies have neither the power nor the competence to pass on the constitutionality of statutes.'').

protect the record from disclosure to non-government parties or the public. The TSOB Review Panel will review materials in the record containing classified information or SSI in camera or during an ex parte proceeding with TSA.

Section 126.17(b) provides that a TSOB Review Panel may not disclose classified information or SSI, except to government parties and government counsel who have the appropriate security clearance and a need to know the information to be disclosed.

§ 126.19 Filing and Supplementing the Record

Section 126.19(a) requires TSA to file a complete record of administrative proceedings, including a certified and un-redacted transcript of all proceedings before the ALJ and all material filed with the ALJ, with the TSOB Review Panel within 30 calendar days after filing or being served with a notice of appeal. The TSOB Review Panel needs the full record in order to conduct a comprehensive review of the ALJ's decision. To ensure that non-government parties have access to a redacted copy of the transcript of proceedings before the ALJ, this subsection permits non-government parties to file a motion requesting a redacted copy of any part of the full administrative record that they do not possess.

Section 126.19(b) permits a party to supplement the record presented to the TSOB Review Panel when (i) anything relevant to an issue on appeal occurs or is created after the ALJ issues a decision, or (ii) the party can show good cause for failing to submit material for the record at an earlier stage of the administrative proceedings. As discussed in II.C. above, DHS is adding paragraph (b)(3) to permit the TSOB to remand the case to the ALJ for additional proceedings upon motion of the parties and ''a showing of good cause.''

§ 126.21 Motions

Section 126.21(a) provides the procedures for filing a motion with a TSOB Review Panel. The requirements are the same as those for filing a brief, which are modeled on Rule 28 of the FRAP.

Section 126.21(b) explains the duty to confer with all other parties before filing any motion. If a party seeks relief from a TSOB Review Panel (for example, extension of a deadline), that party must file a motion requesting the relief. Before filing the motion, the party seeking relief must first confer, or make reasonable, good-faith efforts to confer, with all other parties in an effort to obtain their consent to the relief requested. The 2011 procedures do not include this section, but DHS added it to improve efficiency and communications. It is consistent with Rules 26(c)(1) and 37(a)(1) of the Federal Rules of Civil Procedure. After conferring or attempting to confer, the party seeking relief may file the motion with the TSOB Review Panel. The moving party shall state in the motion, or in a certificate attached to the motion, the specific efforts made to confer. The moving party shall also state in the motion the other parties' positions with regard to the relief requested. If no party opposes the relief requested in a motion, the moving party shall include ''Unopposed'' in the motion's title. These provisions are modeled on Local Rules of Practice adopted by many U.S. District Courts, including, for example, the Rules of the United States District Court for the District of Columbia, Local Rule 7(m) (September 2015), Local Rules for the United States District Court, Eastern District of Virginia, Local Civil Rule 7 and Local Criminal Rule 47 (December 1, 2020). They are designed to promote cooperation between the parties and help resolve issues quickly and efficiently.

Section 126.21(c) provides for motion hearings using communication technology. As defined in this rule, ''communication technology'' means telephone or a videoconferencing platform. Using videoconferencing to conduct motion hearings allows a TSOB Review Panel to efficiently resolve motions without burdening the parties. The Review Panel will consider the availability of adequate security protocols in making determinations concerning motions hearings.

Section 126.21(d) gives a TSOB Review Panel discretion to grant or deny a motion at any time after it is filed. This provision allows a Review Panel to quickly and efficiently resolve routine motions (for example, motions for an extension of a deadline) without waiting for all parties to file a response.

Section 126.21(e) permits a TSOB Review Panel to establish additional procedural requirements regarding motion practice in response to the exigencies of a particular appeal. Additional procedural requirements apply on a case-by-case basis. For example, if a motion raises an unusually complex issue, a Review Panel may find it appropriate to allow the non-moving parties to file a response that is longer than the default 35-page limit. Section 126.21(e) gives the Review Panel the discretion to modify the page limit. This discretion is crucial to establishing an efficient review process. Section 126.21(e) provides two other examples of additional procedural requirements that a Review Panel may wish to adopt in a particular case: time periods for filing responses and replies to motions and a deadline for concluding all motion practice. These examples are illustrative and not intended as an exhaustive list of permissible additional procedural requirements for motion practice. Section 126.21(e) only concerns basic procedural requirements regarding motion practice, and it does not afford a TSOB Review Panel discretion to adopt procedural requirements unrelated to motion practice or to fundamentally change the review process prescribed in this part. A TSOB Review Panel will communicate specific additional procedural requirements regarding motion practice to the parties during proceedings or by serving them with orders.

§ 126.23 Briefs

Section 126.23(a) and (b) enumerate the procedures and deadlines for filing briefs with a TSOB Review Panel. These subsections are modeled after Rule 28 of the FRAP. A party appealing the ALJ's decision (an appellant) must perfect the appeal by filing a brief within 60 calendar days after the date on which the TSA files the administrative record. An appellant's brief must contain a specific list of objections to the ALJ's decision. This requirement is modeled after Rule 28(a)(9) of the FRAP, which requires appellants to clearly list and describe their contentions. A party not appealing the ALJ's decision (an appellee) may file a brief in response to an appellant brief within 30 calendar days after being served with the appellant brief.

Section 126.23(c) provides the specific form for submitting briefs to a TSOB Review Panel. The specifications are modeled on Rule 28 of the FRAP, and they are intended to facilitate an efficient process with the least amount of burden to the parties and the Review Panel.

§ 126.25 Oral Argument

Section 126.25 provides for oral argument. A TSOB Review Panel will decide whether to grant oral argument upon receipt of a request for an oral argument contained in a brief pursuant to § 126.23(c)(5). The TSOB Review Panel has discretion to grant or deny a request for oral argument. The Review Panel may also order oral argument on its own initiative if it determines that oral argument is necessary to clarify the parties' arguments or that oral argument will improve the Panel's understanding

of legal or factual issues material to the appeal.

If oral argument is held, the TSOB Review Panel has discretion to choose the method and location. Oral argument will typically be heard in Washington, DC, or via teleconference or videoconference. The TSOB Review Panel will consider expense and inconvenience to the parties, the need for information security, the quality and reliability of available communication technology, and concern for the efficient administration of proceedings when choosing the method and location of oral argument.

Section 126.25(c) provides that the TSOB Review Panel may also establish any necessary procedural rules to ensure the efficient administration of oral argument. This allows the Review Panel to adjust to the exigencies of a particular appeal. For example, the Review Panel may want to grant the parties a longer amount of time for argument if an appeal is complex and involves a large amount of evidence.

Section 126.25(d) provides that classified information and SSI may not be disclosed during oral argument, and that a Review Panel may hold ex parte proceedings to allow TSA to present such information.

§ 126.27 Deliberations and Action

Section 126.27 provides the procedures by which a TSOB Review Panel resolves an appeal. A Review Panel will consider the transcript of the ALJ's hearing, all material that the ALJ considered as part of the record for decision, any properly filed supplemental material, the parties' briefing, and, if applicable, oral argument. The Review Panel's deliberations are closed to the public, and any materials created by Panel members, the TSOB Docket Clerk, and the Panel's appointed counsel for use in deliberations are not part of the final administrative record and may not be disclosed to the public.

A TSOB Review Panel may affirm, reverse, or modify the ALJ's decision. It may also remand the matter to the ALJ with instructions to address particular issues or consider additional testimony or evidence. A TSOB Review Panel requires a simple majority to decide an action. A Review Panel is required to prepare a written explanation of its action and serve it on the parties. The Review Panel will endeavor to act to resolve an appeal and serve a written explanation within 60 calendar days after the last of the following events: (1) receipt of a timely filed appellant brief; (2) receipt of a timely filed appellee brief; or (3) oral argument. If a Panel member disagrees with the Panel's action or reasoning, that member may write a dissenting report to be served with the written explanation. A Review Panel must redact all classified information and SSI from the written explanation before serving it on non-government parties. The written explanation will not be made available to the public through publication.

§ 126.29 Effect of TSOB Review Panel Action

Section 126.29 explains the effect of a TSOB Review Panel action. After the TSOB Review Panel acts to resolve an appeal and serves a written explanation of its action, any person substantially affected by the action, or the TSA Administrator if he decides that the Panel's action will have a significant adverse impact on Federal programs to ensure safety in aviation and air commerce, may obtain judicial review of the action in an appropriate U.S. Court of Appeals. If judicial review is not obtained, the action of the TSOB Review Panel is final and binding on the parties for the purpose of resolving the particular matter under review. As discussed in II. G. above, DHS is adding the statutory citation of 49 U.S.C. 46110 here, which establishes when an appeal must be filed so that litigants have that information.

§ 126.31 Administration of Proceedings

Section 126.31(a) describes the authority of a TSOB Review Panel to adopt additional procedures consistent with those established in this part. This ensures that a Review Panel has the flexibility to adjust to the exigencies of a particular appeal. Additional procedures apply on a case-by-case basis, and a Review Panel will communicate specific additional procedures to the parties during proceedings or by serving them with orders. For example, if a party or a party's counsel suffers from poor health that renders participation in proceedings difficult, a Review Panel may find it appropriate to adopt additional procedures to accommodate such needs. Section 126.31(a) gives the Review Panel the discretion to make the necessary accommodations. This discretion is crucial to establishing an efficient review process. Other examples of exigencies that may necessitate the adoption of additional procedures include unexpected changes to the TSOB office facilities and technical issues that make communication between the parties and a Review Panel difficult. These examples are illustrative and not intended as an exhaustive list of permissible additional procedures. The discretion afforded by § 126.31(a) is similar to that afforded by § 126.21(e) above in that it also does not empower a TSOB Review Panel to fundamentally change the review process prescribed in this part.

Section 126.31(b) provides that proceedings before a TSOB Review Panel are rendered moot and closed if TSA withdraws its Determination of Security Threat. If TSA withdraws its Determination, TSA will notify the TSOB Review Panel of the withdrawal within five calendar days.

Section 126.31(c) provides that TSOB Review Panel proceedings are generally closed to the public. DHS is adding this provision to protect sensitive panel deliberations and discussions, and other kinds of sensitive or protected information from disclosure, including information regarding the conduct of individuals impacted by a Determination of Security Threat and witnesses to that conduct that may adversely impact these respective individuals' privacy interests. The Review Panel may, at its discretion, decide to open its proceedings to the public. No classified information, SSI or other protected information will be released during an open hearing.

IV. Regulatory Analyses

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 (Regulatory Planning and Review), as amended by Executive Order 14094 (Modernizing Regulatory Review), and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by OMB.

To evaluate properly the benefits and costs of regulations, it is important to define the baseline. DHS evaluates the impacts of this rule against both a no action and pre-statutory baseline. According to OMB Circular A–4, the no action baseline is what the world would

be like if the rule is not adopted.[12] The pre-statutory baseline is what the world would be like if the relevant statute(s) had not been adopted.

Relative to the pre-statutory baseline, the IFR and this final rule increase costs. The statute mandates that an appeal from a decision of an ALJ is made to the TSOB Review Panel. The law provides the benefits of appeal, but it also requires government time to manage and execute the panel's responsibilities, time of the parties to the appeal, and time and potential associated legal fees for the appellant. The government also incurred costs in 2011 developing the procedures for use by the TSOB Review Panel. As of the date of this publication, the panel has reviewed two requests for appeal. The 2011 and 2021 Review Panels relied on the 2011 procedures, but applied different standards of review.

Without the IFR or this final rule, the TSOB still has the authority and duty to review appeals. As discussed above, a TSOB Review Panel has issued two decisions based upon the 2011 procedures. Significant attorney time and resources were spent developing the procedures used in those cases. In the absence of a codified set of procedural rules, this developmental process might need to be repeated each time an appeal is filed with the TSOB. While DHS believes the IFR did not impose any new costs (given that TSOB Review Panels would continue to issue decisions even if this rule was not promulgated), publication of the IFR did provide several benefits which are discussed qualitatively below.

Codifying TSOB Review Panel procedures before the conclusion of presently pending and future ALJ proceedings eliminate the need to rely on the 2011 procedures. In addition, codifying TSOB Review Panel procedures serves the public's interest in government transparency, consistency in administrative review processes, and certainty of expectations regarding government operation. In the absence of codified procedures, the public would not have notice of the details regarding how a TSOB Review Panel is selected and operates, and U.S. citizens who may be adversely affected by FAA certificate action would not have a complete picture of the administrative process by which they may challenge TSA's Determination of Security Threat. Codified procedures allow the public to be informed about the operation of the Federal Government. Codification also provides certainty to U.S. citizens who may be adversely affected by FAA certificate action. This allows them to make informed decisions about whether to challenge TSA's Determination, instill confidence that they will have a full and fair opportunity to be heard, and plan for the entire administrative review process. Codified procedures provide the public with confidence that all appeals will be reviewed in the same manner.

In addition, in this final rule, DHS makes four changes to the IFR in response to public comment. DHS is adding a citation to establish when an appeal must be filed, which will provide litigants with the information necessary to ensure timely appeals. DHS is adding a definition of the term ''substantial evidence,'' which will provide clarity for all parties on the standard of review. DHS is adding language to establish how allow litigants may consent to service via electronically/electronic service, which will make it easier for litigants to do so. Finally, DHS is adding language to provide a process to seek remand for a ''showing of good cause.'' Ensuring there is good cause to grant a motion to supplement the record through remand to the ALJ will ensure that additional proceedings are undertaken only when there is substantive reasoning for them.

B. Regulatory Flexibility Act Assessment

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, title II, 110 Stat. 847, 857–74, requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. However, when a rule is exempt from APA notice and comment requirements the RFA does not require an agency to prepare a regulatory flexibility analysis. Because this rule does not trigger APA notice and comment requirements, DHS is exempt from preparing a regulatory flexibility analysis for this rule. DHS does note, however, that this rule regulates individuals, and individuals are not small entities as contemplated by the RFA.

C. Unfunded Mandates Reform Act of 1995

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

D. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by the Small Business Regulatory Enforcement Fairness Act of 1996. 5 U.S.C. 804(2). This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

E. Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 Civil Justice Reform

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

G. Paperwork Reduction Act Assessment

This interim final rule does not call for a collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.* This rule falls under the category of an administrative action or investigation involving an agency against specific individuals or entities and is therefore excluded from Paperwork Reduction Act requirements. 44 U.S.C. 3518(c)(1)(B) and 5 CFR 1320.4(a).

List of Subjects in 6 CFR Part 126

Administrative practice and procedures, Appeals, Penalties, Reporting and recordkeeping requirements, Security measures.

The Amendments

For the reasons set forth in the preamble, the Department of Homeland Security adds part 126 to Title 6, Code of Federal Regulations, to read as follows:

[12] *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.*

PART 126—TRANSPORTATION SECURITY OVERSIGHT BOARD REVIEW PANEL PROCESS AND PROCEDURES

Sec.

126.1 Purpose and scope.
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126.27 Deliberations and action.
126.29 Effect of TSOB Review Panel action.
126.31 Administration of proceedings.

Authority: 49 U.S.C. 115, 46111; Department of Homeland Security Delegation No. 7071.1.

§ 126.1 Purpose and scope.

This part establishes the procedures by which a Transportation Security Oversight Board (TSOB) Review Panel reviews and acts to resolve an appeal from an Administrative Law Judge (ALJ) decision regarding a Determination of Security Threat made by the Administrator of the Transportation Security Administration (TSA).

§ 126.3 Definitions.

Classified information has the meaning given to that term in Executive Order 13526 or any successor Executive Order.

Communication technology means telephone or a videoconferencing platform.

Other protected information means other information that the government is authorized by statute, regulation, or Executive order to withhold.

Sensitive Security Information (SSI) means information described in 49 CFR 1520.5.

Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

Transportation Security Oversight Board (TSOB) means the board established pursuant to 49 U.S.C. 115.

Transportation Security Oversight Board (TSOB) Review Panel means the panel established pursuant to 49 U.S.C. 46111(d) to consider an appeal from a decision of an administrative law judge as the result of a hearing under 49 U.S.C. 46111(b).

§ 126.5 Appointment of TSOB Review Panel and TSOB Docket Clerk.

(a) Upon request by the Chairman of the TSOB, TSOB members will designate at least one official who meets the criteria in paragraphs (a)(1) through (5) of this section to participate in a TSOB Review Panel pool for a period of two years. The Review Panel nominees must—

(1) Be a member of the Senior Executive Service (SES) or a Senior Level (SL) employee;

(2) Hold a security clearance commensurate with the record under review;

(3) Not be employed by TSA or the Federal Aviation Administration (FAA);

(4) To the extent practicable, have a legal background and be engaged in the practice of law on behalf of the United States Government; and

(5) To the extent practicable, be familiar with transportation security issues.

(b) Upon the expiration of each two-year period, TSOB members will again designate officials to participate in the TSOB Review Panel pool.

(c) The General Counsel of the Department of Homeland Security, or the General Counsel's designee, will appoint an individual from within the Office of the General Counsel to serve as the TSOB Docket Clerk. The TSOB Docket Clerk will serve as the TSOB Review Panel's point of contact for both the public and the parties to ALJ proceedings.

(d) When the TSOB Docket Clerk receives a properly and timely filed appeal from an ALJ's decision, the TSOB Chairperson selects at least three individuals from the TSOB Review Panel pool to serve on a Review Panel to review the ALJ's decision. The TSOB Chairperson has discretion to choose which individuals from the pool will serve on a TSOB Review Panel. In making selections for a TSOB Review Panel, the TSOB Chairperson will consider selecting at least one person with the qualifications set out in paragraph (a)(4) of this section to serve as a Panel Member, and will consider, based upon the composition of the pool as well as the issues raised in the appeal, appointing more than one person with the qualifications set out in paragraph (a)(4) to the TSOB Review Panel.

§ 126.7 Function of TSOB Review Panel.

A TSOB Review Panel reviews an ALJ's decision regarding a Determination of Security Threat issued by the TSA Administrator and may affirm, modify, or reverse the ALJ's decision. The TSOB Review Panel also may remand the matter to the ALJ with instructions to address particular issues or consider additional testimony or evidence.

§ 126.9 Scope of review.

(a) A TSOB Review Panel reviews an ALJ's decision to address whether the decision is supported by substantial evidence in the record before the TSOB Review Panel.

(b) A TSOB Review Panel will not consider the constitutionality of any statute, regulation, Executive order, or order issued by the TSA.

§ 126.11 Counsel.

(a)(1) Parties to proceedings before a TSOB Review Panel may be represented by an attorney who is in good standing with the bar of any State, district, territory, or possession of the United States. Parties desiring representation must obtain such representation at their own expense.

(2) TSA will designate counsel to represent TSA before a TSOB Review Panel. The attorney must hold a security clearance that enables access to all materials related to the appeal.

(b) The General Counsel of the Department of Homeland Security, or the General Counsel's designee, will appoint legal counsel to assist a TSOB Review Panel. Counsel appointed to assist the TSOB Review Panel will facilitate communication between the TSOB Docket Clerk and the TSOB Review Panel, and assist with legal research and drafting for the Panel, as needed. Appointed counsel must hold a security clearance that enables access to all materials related to the appeal.

§ 126.13 Notice of appeal and service.

(a) *Notice of appeal.* A party seeking review of the ALJ's decision must file a notice of appeal with the TSOB Docket Clerk electronically at *TSOB_docket@hq.dhs.gov* or via certified U.S. mail at ATTN: TSOB Docket Clerk, Office of the General Counsel, Department of Homeland Security, Washington, DC, 20528–0485. A notice of appeal must be filed within 60 calendar days of the date of issuance of the ALJ's written decision.

(b) *Service.* To file any document with a TSOB Review Panel, a party must send the document to the TSOB Docket Clerk electronically at *TSOB_docket@hq.dhs.gov,* or via certified U.S. mail at ATTN: TSOB Docket Clerk, Office of the General Counsel, Department of Homeland Security, Washington, DC, 20528–0485. Parties are strongly encouraged to file all documents and consent to electronic service. A party may consent to electronic service by

filing a document expressly stating such a preference with the TSOB Docket Clerk and serving a copy on all other parties. Any document filed with the TSOB Docket Clerk (except a notice of protected information, the administrative record, ex parte motions, and documents containing classified information, Sensitive Security Information (SSI), or other protected information that accompanies a motion to supplement the record) must also be served on all other parties by certified U.S. mail or electronically/electronic service.

(c) *Filing date.* For purposes of all deadlines in this part, the date of filing of a notice of appeal or any document filed with a TSOB Review Panel is the date on which the document is received by the TSOB Docket Clerk.

(d) *Untimely appeals.* A TSOB Review Panel must reject and summarily dismiss a notice of appeal that is filed more than 60 calendar days after the date of issuance of the ALJ's written decision. A TSOB Review Panel may, in its discretion, accept an untimely notice of appeal upon a written showing of good cause for failure to meet the filing deadline.

(e) *Failure to perfect the appeal.* A TSOB Review Panel may dismiss an appeal, on its own initiative or upon motion of any party, when a party has filed a notice of appeal but failed to perfect the appeal by timely filing a brief in accordance with § 126.23.

(f) *Effect of dismissal of appeal.* Where an appeal is dismissed in accordance with paragraphs (d) or (e) of this section the ALJ's written decision becomes final.

§ 126.15 Entry of appearance.

(a) All parties to a proceeding before a TSOB Review Panel must enter their appearances in writing with the TSOB Docket Clerk within 15 calendar days after filing or being served with a notice of appeal. A party's written notice of entry of appearance must identify counsel, if applicable.

(b) Counsel beginning representation of a party after that party has already entered an appearance must file a separate notice of entry of appearance within 15 calendar days of beginning representation.

§ 126.17 Procedures for classified information, Sensitive Security Information (SSI), and other protected information.

(a) *Notice of protected information.* Within 30 calendar days of filing or being served with a notice of appeal, TSA must file a notice of protected information indicating whether the record of proceedings before the ALJ contains classified information, SSI, or other protected information. The notice of protected information must be filed with the TSOB Docket Clerk in accordance with § 126.13(b). If the TSA presented classified information, SSI, or other protected information to the ALJ at an ex parte proceeding or provided such information for in camera review during the ALJ proceedings, then the TSOB Review Panel will also consider that information at an ex parte proceeding or in camera.

(b) *Access to protected information.* A TSOB Review Panel may not disclose Classified Information or other protected information to any non-government party or counsel. A TSOB Review Panel may not disclose SSI to any non-government party or counsel unless the TSA has determined that the party had a preexisting need to know specific SSI as a covered person pursuant to 49 CFR 1520.7 and 1520.11.

§ 126.19 Filing and supplementing the record.

(a) *Filing the record.* The TSA must file a complete record of administrative proceedings, including a certified and unredacted transcript of all proceedings before the ALJ (including ex parte proceedings) and all material filed with the ALJ (including material containing classified information, SSI, or other protected information that was reviewed by the ALJ in camera), with the TSOB Docket Clerk within 30 calendar days after filing or being served with a notice of appeal. Upon motion filed by the TSA, or on its own initiative, the TSOB Review Panel may extend the time to file the record. The TSOB Docket Clerk notifies all parties of the date when the record is filed. Within 30 calendar days of the date the record is filed, non-government parties may file a motion requesting that the TSA provide them with a redacted copy of any part of the record (excluding ex parte proceedings and materials reviewed in camera) that they do not possess. The TSA redacts classified information or other protected information from any part of the record it provides to non-government parties, except to the extent that the TSA has determined that the party had a preexisting need to know specific SSI as a covered person pursuant to 49 CFR 1520.7 and 1520.11.

(b) *Supplementing the record.* (1) A party may file a motion to supplement the record when anything relevant to an issue on appeal occurs after the ALJ issued a decision, or the party can show good cause, as determined by the TSOB Review Panel, for failing to submit material for the record at an earlier stage of the administrative proceedings. When the TSA seeks to supplement the record with material that contains classified information, SSI or other protected information, it may file a motion to supplement the record ex parte.

(2) A TSOB Review Panel may grant a motion to supplement the record when it finds that the supplemental material is relevant to an issue on appeal and that a condition described in paragraph (b)(1) of this section applies.

(3) A TSOB Review Panel may grant a motion to supplement the record by remanding the case to the ALJ for additional proceedings, where good cause is shown.

§ 126.21 Motions.

(a) *Form of motions.* (1) A motion filed with a TSOB Review Panel must comply with the requirements set forth in § 126.23(c)(1) through (4).

(2) Motions must be filed with the TSOB Docket Clerk and served on all parties in accordance with § 126.13(b). The TSOB Docket Clerk provides all motions to the TSOB Review Panel.

(b) *Duty to confer.* Before filing any motion, a party must confer or make reasonable, good-faith efforts to confer with all other parties to resolve the issues that are the subject of the motion. The moving party must state in the motion, or in a certificate attached to the motion, the specific efforts made to comply with this duty to confer. The moving party must also state in the motion the other parties' positions with regard to the relief requested. If no party opposes the relief requested in a motion, the moving party includes ''Unopposed'' in the motion's title. TSA does not have a duty to confer before filing an ex parte motion, but must provide notice to all parties that it has made an ex parte filing.

(c) *Motion hearings.* Upon request of any party, or on its own initiative, a TSOB Review Panel may order the parties to appear for a hearing on any motion that was not filed ex parte. Motion hearings may be conducted via communication technology unless all parties agree to appear in person or the TSOB Review Panel in its discretion determines that an in person appearance is necessary for efficient administration of the hearing. The Review Panel considers expense and inconvenience to the parties, the importance of information security, and the quality and reliability of available communication technology when making these determinations.

(d) *Disposition.* A TSOB Review Panel may, consistent with the requirements of due process and after providing the opposing party with an opportunity to

review and respond, grant or deny a motion at any time after it is filed.

(e) *Additional procedural requirements for motion practice.* A TSOB Review Panel has discretion to establish via order served on the parties, additional procedural requirements regarding motion practice in response to the exigencies of a particular appeal. Such requirements may include, for example, time periods for filing responses and replies, a deadline for concluding all motion practice, and page limitations different from the default 35-page limit established in § 126.23(c)(3). A TSOB Review Panel may not require disclosure of classified information, SSI, or other protected information.

§ 126.23 Briefs.

(a) *Appellant brief.* (1) A party appealing the ALJ's decision must perfect the appeal by filing an appellant brief with the TSOB Docket Clerk and serving that brief on all other parties in accordance with § 126.13(b) within 60 calendar days after the date on which TSA files the record in accordance with § 126.19(a), unless all parties consent to an extension of the filing deadline and provide notice of such agreement to the TSOB Docket Clerk or the TSOB Review Panel extends the filing deadline upon a motion by the appellant.

(2) The appellant brief must enumerate the appellant's objections to the ALJ's decision.

(b) *Appellee brief.* Within 30 calendar days after being served with an appellant brief, a party may file an appellee brief in response with the TSOB Docket Clerk. Any such brief must be served on all other parties in accordance with § 126.13(b) at the same time it is filed with the TSOB Docket Clerk. The parties may consent to an extension of the filing deadline and provide notice of such agreement to the TSOB Docket Clerk or the TSOB Review Panel may extend the deadline for filing an appellee brief upon a motion by the appellee.

(c) *Brief requirements.* A brief submitted to a TSOB Review Panel must adhere to the following specifications:

(1) The brief must be typewritten in Times New Roman, 12-point font, double-spaced, and, if submitted as a hard copy via certified U.S. mail, must be printed single-sided on 8 1/2-by-11 inch paper;

(2) The brief must set forth the name, address, email address, and telephone number of the party or attorney filing it;

(3) The brief must contain no more than 35 pages of text (excepting any tables, appendices, or cover sheets) unless prior permission to file excess pages has been granted by the TSOB Review Panel after consideration of a duly filed motion showing good cause as determined by the TSOB Review Panel;

(4) If submitted as a hard copy via certified U.S. mail, the brief must be bound in any manner that is secure, does not obscure the text, and permits easy reproduction; and

(5) If oral argument is desired, the brief should contain a request for oral argument that explains why oral argument will contribute substantially to the development of an issue on appeal.

§ 126.25 Oral argument.

(a) Upon receipt of a request from any party contained in a brief or in a motion, or on its own initiative, a TSOB Review Panel may order the parties to present oral argument. The Review Panel orders oral argument if it determines that oral argument will contribute substantially to the development of an issue on appeal.

(b) A TSOB Review Panel has discretion, within the requirements of all relevant statutory and regulatory provisions for information security, to choose the method and location of oral argument. The Review Panel will consider expense and inconvenience to the parties, the importance of information security, the quality and reliability of available communication technology, and concern for the efficient administration of proceedings when establishing the method and location of oral argument.

(c) A TSOB Review Panel has discretion to structure and establish procedural rules for oral argument via order served on the parties. Such rules may include time limits for argument and the order in which parties present argument.

(d) Classified information, SSI, or other protected information may not be disclosed during oral argument. A TSOB Review Panel may hold ex parte proceedings to allow for the presentation of classified information, SSI, or other protected information.

§ 126.27 Deliberations and action.

(a) *Deliberations.* TSOB Review Panel deliberations are closed proceedings. Any materials created by Review Panel members, the TSOB Docket Clerk, and the Review Panel's appointed counsel for use in deliberations are not part of the final administrative record.

(b) *Action.* A TSOB Review Panel may affirm, modify, or reverse the ALJ's decision. It may also remand the matter to the ALJ with instructions to address particular issues or consider additional testimony or evidence.

(1) A TSOB Review Panel requires a simple majority to decide an action.

(2) In case of a disagreement among TSOB Review Panel members, a dissenting report may be served with the written explanation of the Review Panel's action. A dissenting report must be prepared in accordance with the requirements for the Review Panel's written explanation.

(c) *Written explanation.* A TSOB Review Panel will explain its action in writing to the maximum extent permitted by prudent concern for the national security interests of the United States and applicable laws and regulations governing information disclosure. If necessary, the Review Panel may prepare its written explanation in both a protected format (which may contain classified information, SSI, and other protected information) and a non-protected format (which must not contain classified information, SSI, and other protected information). The Review Panel serves non-government parties with the non-protected written explanation and government parties with the protected written explanation. The Review Panel is prohibited from providing the protected written explanation to non-government parties; however, the protected written explanation, if any, is part of the final administrative record that TSA must submit to a U.S. Court of Appeals in the event that a party seeks judicial review of the Review Panel's action.

(d) *Timing.* A TSOB Review Panel endeavors to resolve an appeal and issue a written explanation of its action to the parties no later than 60 calendar days after the last of the following events:

(1) Receipt of a timely filed appellant brief;

(2) receipt of a timely filed appellee brief; or

(3) Oral argument.

§ 126.29 Effect of TSOB Review Panel action.

(a) Any person substantially affected by a TSOB Review Panel's action, or the TSA Administrator when he or she decides that the Panel's action will have a significant adverse impact on carrying out 49 U.S.C. subtitle VII, part A, may obtain judicial review in an appropriate U.S. Court of Appeals in accordance with 49 U.S.C. 46110. The Administrators of the FAA and TSA must be made parties to any civil action filed in a U.S. Court of Appeals seeking review of a TSOB Review Panel action.

(b) If judicial review is not obtained, the action of the TSOB Review Panel is final and binding on the parties for the purpose of resolving the particular decision under review.

§ 126.31 Administration of proceedings.

(a) A TSOB Review Panel has authority to govern the conduct of its proceedings and internal operations by establishing any additional rules or procedures that are not inconsistent with this part.

(b) If TSA withdraws its Determination of Security Threat at any time after a notice of appeal has been filed pursuant to § 126.13(a), the proceedings before the TSOB Review Panel are rendered moot and closed. TSA must file a notice of withdrawal of the Determination of Security Threat with the TSOB Docket Clerk within five calendar days of such withdrawal.

(c) TSOB Review Panel proceedings will generally be closed to the public. A TSOB Review Panel may, in its discretion, open its proceedings to the public. Classified information, SSI, or other protected information shall not be disclosed during administrative proceedings, in accordance with § 126.25(d).

Alejandro Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2024–05131 Filed 3–8–24; 11:15 am]

BILLING CODE 9110–9B–P

CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part X

Consumer Financial Protection Circular 2024–01: Preferencing and Steering Practices by Digital Intermediaries for Consumer Financial Products or Services

AGENCY: Consumer Financial Protection Bureau.

ACTION: Consumer financial protection circular.

SUMMARY: The Consumer Financial Protection Bureau (Bureau or CFPB) has issued Consumer Financial Protection Circular 2024–01, titled, ''Preferencing and steering practices by digital intermediaries for consumer financial products or services.'' In this circular, the Bureau responds to the question, ''Can operators of digital comparison-shopping tools or lead generators violate the Consumer Financial Protection Act (CFPA) by preferencing products or services based on financial or other benefits to the operator?''

DATES: The Bureau released this circular on its website on February 29, 2024.

ADDRESSES: Enforcers, and the broader public, can provide feedback and comments to *Circulars@cfpb.gov.*

FOR FURTHER INFORMATION CONTACT: George Karithanom, Regulatory Implementation & Guidance Program Analyst, Office of Regulations, at 202–435–7700 or at: *https://www.reginquiries.consumerfinance.gov/*. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

Question Presented

Can operators of digital comparison-shopping tools or lead generators violate the Consumer Financial Protection Act (CFPA) by preferencing products or services based on financial or other benefits to the operator?

Response

Yes. Operators of digital comparison-shopping tools can violate the prohibition on abusive acts or practices if they distort the shopping experience by steering consumers to certain products or services based on remuneration to the operator. Similarly, lead generators can violate the prohibition on abusive practices if they steer consumers to one participating financial services provider instead of another based on compensation received. Where consumers reasonably rely on an operator of a digital comparison-shopping tool or a lead generator to act in their interests, the operator or lead generator can take unreasonable advantage of that reliance by giving preferential treatment to their own or other products or services through steering or enhanced product placement, for financial or other benefits.

Background

For many households, the process of shopping for a financial product or service now includes interactions with digital intermediaries. These intermediaries include websites, applications, or chatbots that operate as comparison-shopping tools, which consumers turn to for help with researching, comparing, and selecting consumer financial products or services. Offering a comparison-shopping tool for consumers and generating leads for financial companies can and sometimes do operate as distinct business models, and for the purposes of this circular, comparison-shopping tools and lead generators are discussed separately. However, consumers often interact with them in similar ways and many digital intermediaries operate as both, presenting themselves as consumer-serving comparison-shopping tools while simultaneously increasing profits by directing leads based on financial benefit. Digital intermediaries commonly receive remuneration or other benefits, sometimes referred to as ''bounties'' by market participants.

Digital Comparison-Shopping Tools

Consumers are increasingly using digital comparison-shopping tools to find consumer financial products or services that fit their interests.[1] These tools facilitate comparison shopping by presenting information about the costs, features, or other terms for a set of comparable financial products or services, such as credit cards, student loans, and savings accounts, offered by different providers. In addition to presenting options offered by third-party providers of financial products and services, some operators of digital comparison-shopping tools offer their own financial products and services and include their own options in the comparison-shopping tool.

Comparison-shopping information can be presented in a static or interactive format. In the latter case, some operators allow people who use the tool to sort options based on different criteria or to otherwise customize the presentation of information and options (sometimes after a default presentation). Also, some operators collect information from consumers and then purport to provide a list of options tailored to the consumers' particular circumstances or preferences. In other cases, operators just present an ordered list of recommended providers. Increasingly,

[1] As used in this circular, the term ''digital comparison-shopping tools'' includes both tools that overtly recommend certain products as well as tools that have the effect of affirmatively influencing consumers' likelihood of selecting or engaging with information about various consumer financial products and services. The term encompasses ''Digital Mortgage Comparison-Shopping Platforms,'' which are addressed in a recent advisory opinion regarding the Real Estate Settlement Procedures Act. *See* Digital Mortgage Comparison-Shopping Platforms and Related Payments to Operators, 88 FR 9162 (Feb. 13, 2023). The term also encompasses some ''digital marketing providers,'' which are discussed in a recent interpretive rule regarding the CFPA definition of ''service providers.'' *See* Limited Applicability of Consumer Financial Protection Act's ''Time or Space'' Exception with Respect to Digital Marketing Providers, 87 FR 50556 (Aug. 17, 2022). The scope of this circular, however, is different than the scope of either of those prior documents. This circular addresses all digital comparison-shopping tools that provide recommendations for or comparisons among any consumer financial products or services and addresses potential violations under the abusive prong of the CFPA.

digital comparison-shopping tools are using algorithms that order recommendations or ranking lists based on multiple variables, such as consumer characteristics, product features, consumer ratings, the likelihood a consumer would be approved, various click-through and application completion or approval rates, and provider compensation or bids.

Operators of digital comparison-shopping tools enter various types of commercial arrangements with providers of consumer financial products and services that participate in a comparison-shopping tool. Some operators receive revenue in exchange for the provision of time or space for advertising that is clearly set apart from the content of the comparison-shopping tool, like banner ads or pop-up advertisements.[2] This kind of advertising is not at issue in this circular.

Instead, this circular focuses on compensation arrangements from providers for preferential treatment by an operator of a digital comparison-shopping tool. Operators are sometimes paid by product providers on a fee-per-action basis—for example, by receiving fees per click, per application, per conversion, per offer, or per sale. Often, operators allow firms to bid against each other for advantageous placement by paying bounties, which can be targeted at customers fitting the characteristics a provider wants to acquire or aimed at meeting certain volume goals. The degree to which these bounties affect product placement depends on the operator's business model and the weight given to provider compensation over other factors.

Lead Generation

Lead generators in lending markets sell information about prospective customers to lenders. Lead generators sometimes perform this function without making any contact with the consumer—selling data on consumers as a specialty data broker. But these entities also collect data directly from consumers by advertising websites that present themselves as helping consumers get a loan or connect with lenders.[3]

When consumers submit their information to a lead generator indicating an interest in obtaining a loan, the lead generator sells the consumer's information to lenders to complete a loan transaction. Lead generators decide which lender obtains a lead based on a variety of criteria depending on the firm. They sometimes deploy algorithms to use many variables simultaneously to make these automated decisions, similar to digital comparison-shopping tools. Sometimes lead generators collect more information from consumers to assist lenders in determining whether to purchase a lead, and lead generators sometimes perform underwriting or origination tasks on behalf of partner lenders. In fact, in some cases the automated decision on which a lender obtains a lead can be so quick that the consumer's user experience between navigating to a lead generator's website and obtaining a loan can be continuous.

Similar to compensation agreements for operators of digital shopping tools, lead generators are paid by participating lenders using a variety of pricing models. Payments can similarly be charged as a fee-per-action, such as for each lead, or each completed application. Lenders sometimes pay for a number of leads, or a number of leads meeting certain criteria. And, similarly, some lead generators send leads to providers who bid the highest for a specific type of lead.[4]

Analysis and Findings

The CFPA prohibits covered persons or service providers from engaging in any unfair, deceptive, or abusive act or practice.[5] An act or practice in connection with the provision of a consumer financial product or service is abusive if it ''takes unreasonable advantage'' of certain circumstances, including ''the reasonable reliance by the consumer on a covered person to act in the interests of the consumer.'' [6]

Protecting and facilitating people's ability to effectively compare and choose among options for consumer financial products or services is among the core statutory objectives of the CFPB.[7]

Below, this circular first addresses how an operator of a digital comparison-shopping tool or a lead generator might leverage consumer reliance to take unreasonable advantage of consumers where the operator or lead generator preferences particular providers or products over others in exchange for financial or other benefits to the operator, as opposed to making presentation or lead distribution decisions using other factors not relating to the operator or lead generator's relative compensation from different providers. The circular then provides examples of potentially abusive acts or practices by digital comparison-shopping tool operators.

CFPA Section 1031(d)(2)(C) Elements

Reasonable Reliance by the Consumer on a Covered Person To Act in the Interests of the Consumer

Digital comparison-shopping tool operators and lead generators can qualify as ''covered persons'' under CFPA section 1031(d)(2)(C). An operator or lead generator is a ''covered person'' if it offers or provides consumer financial products or services or is an affiliate of a person that offers or provides consumer financial products or services and acts as a service provider by including those products in the tool or providing leads.[8] Depending on the role that a digital comparison-shopping tool or lead generator plays in a consumer's shopping experience, it may be extending or brokering the credit products that consumers ultimately receive.[9] In addition, some digital comparison-shopping tools and lead generators may be providing financial

[2] Factors that inform whether advertisements are separate from the content of a comparison-shopping tool include whether content is completely visually separate from the presentation of product recommendations or results, such that paid content is not embedded or intertwined with a tool's presentation of product rankings or recommendations, and whether paid content is presented as a recommendation from the comparison-tool operator. However, the question of whether advertising content is separate from a comparison-shopping tool is fact specific and will often include consideration of other factors.

[3] *See, e.g.,* Compl., *FTC* v. *ITMedia Sols. LLC,* No. 2:22–cv–00073 (C.D. Cal. Jan. 5, 2022) (alleging that lead generator unlawfully used a ''loan application'' form to collect consumers' information by deceptively presenting itself as connecting consumers with lenders).

[4] *See, e.g.,* Am. Compl., *CFPB* v. *D & D Marketing, Inc.,* No. 2:15–cv–09692 (C.D. Cal. June 30, 2016) (alleging unfair and abusive acts or practices where lead aggregator ordered sales based primarily on the price providers would pay for leads).

[5] Although this circular focuses on the reasonable-reliance prong of the abusive prohibition, conduct discussed in this circular can also violate other prongs of the abusive prohibition under 12 U.S.C. 5531(d), 12 U.S.C. 5531 and 5536(a)(1)(B)'s prohibitions against unfair or deceptive acts or practices, or other Federal, State, or local laws.

[6] 12 U.S.C. 5531(d)(2)(C). *See generally* CFPB, *Policy Statement on Abusive Acts or Practices,* at 17–18 (April 3, 2023), *https://files.consumerfinance.gov/f/documents/cfpb_policy-statement-of-abusiveness_2023-03.pdf* (discussing reasonable-reliance abusive prong).

[7] Under the CFPA, a central purpose of the CFPB is to promote ''fair, transparent, and competitive'' markets. 12 U.S.C. 5511(a). Moreover, CFPA legislative history highlights that an important purpose of the CFPB is to ensure that ''a consumer can shop and compare products based on quality, price, and convenience without having to worry about getting trapped by the fine print into an abusive deal.'' S. Rep. No. 111–176, at 11, 229 (2010).

[8] *See* 12 U.S.C. 5481(6) (defining ''covered person''); 12 U.S.C. 5481(26) (defining ''service provider'').

[9] *See* 12 U.S.C. 5481(5), (15)(A)(i).

advisory services to consumers as well.[10]

Additionally, some operators or lead generators offer their own version of the consumer financial product or service that consumers seek to compare using the digital comparison-shopping tool or for which leads are generated—for example, where an operator of a credit-card digital comparison-shopping tool offers its own card on the tool. Other operators or lead generators offer consumer financial products or services of a different type from what consumers are using a tool to compare or for which leads are generated—for example, an operator of a credit-card digital comparison-shopping tool might use pop-up advertisements to promote credit-counseling or credit-repair services offered by itself or an affiliate.

Reasonable Reliance

Consumers sometimes reasonably rely on digital comparison-shopping tool operators or lead generators to act in their interests. Operators of digital comparison-shopping tools and lead generators can engender reasonable consumer reliance by virtue of playing the role of helping people select providers. They can also engender reasonable consumer reliance by virtue of their explicit and implicit representations and communications.

In particular, reasonable consumer reliance can exist because of a digital comparison-shopping tool's function in a market, such as when a tool operator assumes the role of acting on behalf of consumers or helping them to select products or services based on the consumer's interests.[11] The nature of people's interactions with the tool informs an evaluation of the digital comparison-shopping tool's function in the market. For example, consumers may reasonably rely on a tool that functions by ''matching'' people with consumer financial products or services, *i.e.,* providing curated recommendations based partly on information provided by the consumer.

In addition, if an operator explicitly or implicitly holds its tool out as presenting information based on the interests of the consumer, it may be reasonable for consumers to rely on the tool to function accordingly. A tool operator sometimes explicitly holds itself out as presenting information based on the interests of the consumer by directly stating so, such as by, for example, claiming its recommendations are objective.

An operator can also implicitly hold itself out as presenting information based on the interests of the consumer even if it does not explicitly claim to make objective recommendations. For example, the operator may emphasize its ''expertise'' in helping consumers evaluate options; describe its tool as providing ''research-based'' rankings of options for consumers; state to consumers that it will ''help you today'' to ''achieve your financial goals''; purport to match consumers with the ''best'' or ''right'' offers; or claim to ''put consumers first'' or to provide a ''one stop shop'' with all the information consumers need to make informed selections among potential providers.

In some contexts, background conditions, such as an association with a trusted institution, could factor into consumers' reasonable reliance on a digital comparison-shopping tool (*e.g.,* a financial aid and student loan advisory website that is associated with a college or university).[12] Other factors, such as evidence that consumers using the tool tend to not understand that elements of the tool's rankings or recommendations are influenced by financial considerations, also contribute to establishing the existence of reasonable consumer reliance.

Relatedly, consumer-facing lead generators can engender reasonable consumer reliance within the meaning of CFPA section 1031(d)(2)(C) through their role as intermediating between consumers and lenders and their explicit or implicit communications to consumers. In particular, when lead generators conceal their real role in the market and present themselves as a tool for consumers to connect with trusted lenders or receive the best available terms for a consumer financial product or service, given the consumer's individual circumstances, a consumer would likely be reasonable in relying on the entity to act in the consumer's interests.[13]

Interests of the Consumer

Adjusting a digital comparison-shopping tool's presentation of consumer financial products and services based on fees or other benefits to tool operators will often not be in the interests of the consumer. In many cases where consumers use digital comparison-shopping tools, consumers have an interest in navigating a complex financial market to obtain products that are best for them. Consumer interests are not served when they are steered toward more expensive or less favorable products because those products are offered by the tool operator or its affiliates or because those products generate more revenue for the tool operator.

Similarly, consumer interests are not served when consumers are steered to more expensive or less favorable products by lead generators because one provider is bidding more for the lead than another.[14]

Unreasonable Advantage

A digital comparison-shopping tool operator or lead generator can take unreasonable advantage of the reasonable consumer reliance described above when they operate a business model that gives preferential treatment, such as through steering, to particular consumer financial products or services to increase financial or other benefits to the tool operator. For example, the operator may be taking unreasonable advantage of the consumer's reasonable reliance if the operator is able to generate more interest in its own financial products or services or is able to increase fees charged to third-party providers because the tool functions in a way that engenders the consumer's reasonable, but misguided, reliance on the tool to present information in a manner consistent with the interests of the consumer. In addition, benefits that accrue to the operator or lead generator include direct financial compensation or indirect or non-financial benefits, such as the ability to gather data that indirectly increases the operator's or lead generator's ability to obtain financial or other benefits.[15]

[10] *See* 12 U.S.C. 5481(5), (15)(A)(viii).

[11] *See generally* CFPB, *Policy Statement on Abusive Acts or Practices,* at 17–18 (April 3, 2023), *https://files.consumerfinance.gov/f/documents/cfpb_policy-statement-of-abusiveness_2023-03.pdf.*

[12] Additionally, a comparison-shopping site operator or lead generator can also attempt to generate trust and reliance by falsely presenting a relationship with a trusted institution. *See, e.g.,* CFPB, *Consumer Financial Protection Circular 2022–02: Deceptive representations involving the FDIC's name or logo or deposit insurance* (May 17, 2022), *https://www.consumerfinance.gov/compliance/circulars/circular-2022-02-deception-representations-involving-the-fdics-name-or-logo-or-deposit-insurance/* (CFPB circular addressing deceptive misuse of the FDIC logo in representations about deposit insurance); Compl., *FTC* v. *Career Education Corporation,* No. 1:19–cv–05739 (N.D. Ill. Aug. 27, 2019) (Career Education Corporation purchased sales from lead generators that falsely represented they were affiliated with the U.S. military).

[13] *See, e.g.,* Compl., *FTC* v. *ITMedia Sols. LLC.*

[14] *See, e.g.,* Compl., *FTC* v. *Blue Global, LLC,* No. 2:17–cv–2117 (D. Ariz. July 3, 2017) (Blue Global collected loan applications and promised to match consumers with loans that had the best interest rates, finance charges, and repayment periods when, in fact, they indiscriminately sold leads.).

[15] *See* CFPB, *Policy Statement on Abusive Acts or Practices,* at 8 (April 3, 2023), *https://files.consumerfinance.gov/f/documents/cfpb_policy-statement-of-abusiveness_2023-03.pdf* (discussing monetary and

Enforcers should closely examine the specific details of bounty or bidding schemes when making a determination of abusive conduct. If a digital comparison-shopping tool operator or lead generator requires providers to bid or set bounties for leads, and that compensation scheme increases overall revenue while impacting placement on a comparison-shopping website or mobile app or impacting who receives leads, that can suggest that the operator or lead generator is violating the prohibition on abusive acts or practices. The reason is commonsensical: if the tool operator or lead generator receives a higher fee from one provider than another and provides preferential treatment as a result, this can suggest that the lead generator or operator is making decisions based on its own benefit and not in consumers' interests. This concern may be somewhat mitigated when a comparison-shopping tool operator or lead generator receives compensation from providers, but does not consider such compensation in its decisions regarding placement or, similarly, regarding which providers receive a lead.[16]

Unreasonable advantage-taking can also occur where the operator benefits by steering consumers toward products or services—including its own or those of its affiliates—that are more costly or otherwise less desirable than what consumers might otherwise prefer.[17] In addition, it can occur where an operator leverages an affiliation or informal connection with a trusted institution, such as a college or university, to increase the operator's revenue while making recommendations not based on factors likely to be consistent with consumer interests.

Examples of Preferencing or Steering Arrangements

The following is a non-exhaustive list of examples that illustrate arrangements where an operator of a digital comparison-shopping tool or a lead generator steers consumers to certain consumer financial products or services in exchange for financial or other benefits to the operator or lead generator, regardless of the interests of the consumer. These arrangements can be abusive if the operator or lead generator takes unreasonable advantage of the consumer's reasonable reliance on the operator or lead generator to act in the interests of the consumer.

- A tool operator presents a product (or set of products) that is preferred because of financial considerations in a placement that is more likely to be seen, reflects a preferential ordering, has more dynamic design features, requires fewer clicks to access product information, or otherwise increases the likelihood that a consumer will consider or select the preferred product.[18] This can include self-preferencing where the digital comparison-shopping tool promotes the products or services of the tool operator.
- A tool operator presents certain options as ''featured'' because they are provided by the operator or a third-party provider that paid for enhanced placement.[19]
- A tool operator directs consumers to the products that pay higher fees within a product category—for example, an operator routinely matches consumers with a loan provider because it pays the highest fee per application.
- A tool operator receives different payment based on whether the digital comparison-shopping tool meets a certain threshold volume allocation of leads generated within a set period of time, and uses steering practices to increase the likelihood the operator will satisfy volume allocation requirements. For example, in a 14-day period, a provider pays fees only if at least 1,000 applications are generated, and, on day 13, the operator is more likely to steer consumers to that provider's products until the allocation is met.
- A tool operator or lead generator uses dynamic bidding or a bounty system to determine which offers are presented to consumers with certain demographic or other characteristics.
- A tool operator expressly or implicitly presents the total set of options featured on the tool as relatively comprehensive or based on criteria such as price, terms, quality of service, or security, when in fact the operator determines which options to include based on financial or other benefits obtained by the operator. For example, a set of lenders jointly establish a comparison-shopping tool that appears to present options based on criteria that further the consumer's interests but that actually presents only a subset of products that are offered or provided by those lenders. Some sites preference certain products while also including other products, but with design features that ensure that only the preferred products receive preferred placement, regardless of whether that is in the interests of the consumer.
- A tool operator presents a preferred product as a ''match'' that is not the participating product that is most consistent with the expressed interests of a consumer. A comparison tool can prompt users to input information about their preferences through a survey, filtering options, or interactions with a chatbot. By eliciting input on consumer preferences, the operator creates the impression that results will be presented based on an objective evaluation of those preferences. However, the operator actually presents results based on financial or other benefits to the operator.
- A lead generator guarantees a certain number and quality of leads to multiple participating lenders and divides customers meeting those criteria up without regard to the fact that consumers with similar characteristics are receiving different offers.

About Consumer Financial Protection Circulars

Consumer Financial Protection Circulars are issued to all parties with authority to enforce Federal consumer financial law. The CFPB is the principal Federal regulator responsible for administering Federal consumer financial law, *see* 12 U.S.C. 5511, including the Consumer Financial Protection Act's prohibition on unfair, deceptive, and abusive acts or practices, 12 U.S.C. 5536(a)(1)(B), and 18 other ''enumerated consumer laws,'' 12 U.S.C. 5481(12). However, these laws are also enforced by State attorneys general and State regulators, 12 U.S.C. 5552, and prudential regulators including the Federal Deposit Insurance Corporation, the Office of the Comptroller of the

non-monetary advantages, including ''increased market share, revenue, cost savings, profits, reputational benefits, and other operational benefits'').

[16] A digital comparison-shopping tool operator or lead generator can face greater risk that the exclusion of non-paying providers from its service would constitute an abusive act or practice if a very low number of providers is included within a service. Similarly, in the context of digital mortgage comparison-shopping platforms, the CFPB has advised that, all other things being equal, ''presenting a greater number of comparison options rather than fewer'' generally reduces the risk of a violation of section 8 of the Real Estate Settlement Procedures Act. 88 FR 9162, 9167 (Feb. 13, 2023).

[17] While evidence of harm to consumers can bolster a determination that an entity is taking unreasonable advantage of consumers, the text of CFPA section 1031(d)(2)—in contrast to the definition of ''unfairness'' in CFPA section 1031(c)(1)—does not require ''substantial injury'' to consumers as a prerequisite for establishing abusive conduct. *Compare* 12 U.S.C. 5531(c)(1)(A), *with* 12 U.S.C. 5531(d)(2).

[18] *See generally* FTC, *Bringing Dark Patterns to Light,* at 2 (Sept. 2022) (discussing ''design practices that trick or manipulate users into making choices they would not otherwise have made and that may cause harm'').

[19] Consumers may be less likely to have the impression that a product is being presented as being in the consumer's interest if a tool operator presents sponsored or other advertising content that is completely visually separate from the presentation of product recommendations or results and the advertisement itself is not presented as a recommendation.

Currency, the Board of Governors of the Federal Reserve System, and the National Credit Union Administration. *See, e.g.,* 12 U.S.C. 5516(d), 5581(c)(2) (exclusive enforcement authority for banks and credit unions with $10 billion or less in assets). Some Federal consumer financial laws are also enforceable by other Federal agencies, including the Department of Justice and the Federal Trade Commission, the Farm Credit Administration, the Department of Transportation, and the Department of Agriculture. In addition, some of these laws provide for private enforcement.

Consumer Financial Protection Circulars are intended to promote consistency in approach across the various enforcement agencies and parties, pursuant to the CFPB's statutory objective to ensure Federal consumer financial law is enforced consistently. 12 U.S.C. 5511(b)(4).

Consumer Financial Protection Circulars are also intended to provide transparency to partner agencies regarding the CFPB's intended approach when cooperating in enforcement actions. *See, e.g.,* 12 U.S.C. 5552(b) (consultation with CFPB by State attorneys general and regulators); 12 U.S.C. 5562(a) (joint investigatory work between CFPB and other agencies).

Consumer Financial Protection Circulars are general statements of policy under the Administrative Procedure Act. 5 U.S.C. 553(b). They provide background information about applicable law, articulate considerations relevant to the Bureau's exercise of its authorities, and, in the interest of maintaining consistency, advise other parties with authority to enforce Federal consumer financial law. They do not restrict the Bureau's exercise of its authorities, impose any legal requirements on external parties, or create or confer any rights on external parties that could be enforceable in any administrative or civil proceeding. The CFPB Director is instructing CFPB staff as described herein, and the CFPB will then make final decisions on individual matters based on an assessment of the factual record, applicable law, and factors relevant to prosecutorial discretion.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2024–05141 Filed 3–11–24; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

[Docket ID OCC–2024–0002]

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Docket No. OP–1829]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 323

RIN 3064–ZA41

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 722 and 741

Temporary Exceptions to FIRREA Appraisal Requirements in Maui County as Affected by Hawaii Wildfires

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); and National Credit Union Administration (NCUA), collectively referred to as the agencies.

ACTION: Statement and order; temporary exceptions.

SUMMARY: The Depository Institutions Disaster Relief Act of 1992 (DIDRA) authorizes the agencies to make exceptions to statutory and regulatory appraisal requirements under Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) relating to transactions involving real property located within an area in a state or territory declared to be a major disaster by the President. In this statement and order, the agencies exercise their authority to grant temporary exceptions to the FIRREA appraisal requirements for real estate-related financial transactions, provided certain criteria are met, in an area in the State of Hawaii following the major disaster declared by President Biden as a result of wildfires. The expiration date for the exceptions is August 10, 2026, which is three years after the date the President declared the major disaster.

DATES: This order is effective on March 12, 2024 and expires three years after the date the President declared the relevant area a major disaster, which is August 10, 2026.

FOR FURTHER INFORMATION CONTACT: *OCC:* Kevin Lawton, Appraiser, Real Estate Specialist, Bank Supervision Policy, at (202) 649–7152; or Mitchell Plave, Special Counsel, Chief Counsel's Office, at (202) 649–6285. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Board: Devyn Jeffereis, Senior Financial Institution Policy Analyst II, Division of Supervision and Regulation at (202) 452–2729; Matthew Suntag, Senior Counsel, Legal Division, at (202) 452–3694; or David Imhoff, Senior Attorney, Legal Division, at (202) 452–2249; For users of TTY–TRS, please call 711 from any telephone, anywhere in the United States.

FDIC: Patrick J. Mancoske, Senior Examination Specialist, Division of Risk Management and Supervision, at (202) 898–7032, *PMancoske@FDIC.gov;* Mark Mellon, Counsel, Legal Division, at (202) 898–3884, *MMellon@FDIC.gov;* Lauren Whitaker, Counsel, Legal Division at (202) 898–3872, *lwhitaker@fdic.gov;* Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

NCUA: Simon Hermann, Senior Credit Specialist, Office of Examination and Insurance, at (703) 518–6360; Robert Leonard, Compliance Officer, Office of General Counsel, (703) 518–1143; Rachel Ackmann, Senior Staff Attorney, Office of General Counsel, at (703) 548–2601; National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

Statement

Section 2 of DIDRA, which added section 1123 to Title XI of FIRREA,[1] authorizes the agencies to make exceptions to statutory and regulatory appraisal requirements for certain transactions. These exceptions are available for transactions involving real property located in an area in which the President has determined a major disaster exists, pursuant to 42 U.S.C. 5170, provided that the exception would facilitate recovery from the major disaster and is consistent with safety and soundness.

On August 10, 2023, the President declared that a major disaster existed in the State of Hawaii [2] due to damage resulting from wildfires beginning on August 8, 2023. The agencies have determined that granting relief from the appraisal requirements set forth in Title

[1] 12 U.S.C. 3352.

[2] Press Release, The White House (August 10, 2023), available at *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/08/10/president-joseph-r-biden-jr-approves-hawaii-disaster-declaration-3/.*

XI of FIRREA, and in the agencies' appraisal regulations, for real estate-related financial transactions in an area designated as adversely affected by the major disaster is consistent with the provisions of DIDRA.

Facilitation of Recovery From the Major Disaster

The agencies have determined that the disruption of real estate markets in the area designated as adversely affected by the major disaster interferes with the ability of depository institutions [3] to obtain appraisals that comply with Title XI statutory and regulatory requirements. Further, the agencies have determined that the disruption may impede institutions in making loans and engaging in other transactions that would aid in the reconstruction and rehabilitation of the affected area. Accordingly, the agencies have determined that recovery from this major disaster would be facilitated by exempting certain transactions involving real estate located in the area designated as adversely affected by the wildfires from the real estate appraisal requirements of Title XI of FIRREA and its implementing regulations.[4]

Consistency With Safety and Soundness

The agencies also have determined that the exceptions are consistent with safety and soundness, provided that the depository institution determines the following: (1) the transaction involves real property located in the area designated as adversely affected by the major disaster; (2) there is a binding commitment to fund the transaction [5] that was entered into on or after August 10, 2023, but no later than August 10, 2026; and (3) the value of the real property supports the institution's decision to enter into the transaction. In addition, the transaction must continue to be subject to review by management and by the agencies in the course of examinations of the institution.

Expiration Date

Exceptions made under section 1123 of FIRREA may be provided for no more than three years after the President determines a major disaster exists in an area.[6] Accordingly, the exceptions provided for by this order shall expire three years after the date the President declared a major disaster existed in the State of Hawaii, which is August 10, 2026.

Order

In accordance with section 2 of DIDRA, relief is hereby granted from the provisions of Title XI of FIRREA and the agencies' appraisal regulations for any real estate-related financial transaction that requires the services of an appraiser under those provisions, provided that the institution determines each of the following:

(1) The transaction involves real property located in Maui County,[7] which has been designated as adversely affected by a major disaster by the President as a result of the wildfires beginning on August 8, 2023.

(2) There is a binding commitment to fund the transaction [8] that was entered into on or after August 10, 2023, but no later than August 10, 2026.

(3) The value of the real property supports the institution's decision to enter into the transaction.

Michael J. Hsu,

Acting Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on March 5, 2024.

James P. Sheesley,

Assistant Executive Secretary.

By order of the National Credit Union Administration Board.

Dated at Alexandria, VA, this 28th day of February, 2024.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2024–05159 Filed 3–11–24; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P; 7535–01–P

[3] Depository institutions include federally insured credit unions.

[4] 12 U.S.C. 3331–3355; 12 CFR 34.41–34.47 (OCC); 12 CFR part 225, subpart G (Board); 12 CFR part 323, subpart A (FDIC); 12 CFR part 722 (NCUA).

[5] This relief also includes loans modified during the effective period of this order.

[6] 12 U.S.C. 3352(b).

[7] Press Release, The White House (August 10, 2023), available at *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/08/10/president-joseph-r-biden-jr-approves-hawaii-disaster-declaration-3/.*

[8] This relief also includes loans modified during the effective period of this order.

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1228

RIN 2590–AB30

Exception to Restrictions on Private Transfer Fee Covenants for Loans Meeting Certain Duty To Serve Shared Equity Loan Program Requirements

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA) is adopting as final, without substantive change, a proposed rule amending its regulation that restricts its regulated entities—the Federal National Mortgage Association (Fannie Mae), the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises), and the Federal Home Loan Banks (Banks)—from purchasing, investing in, accepting as collateral, or otherwise dealing in mortgages on properties encumbered by certain types of private transfer fee covenants (PTFCs), or related securities, subject to certain exceptions (PTFC Regulation). As proposed, the final rule establishes an additional exception that authorizes the Enterprises and Banks to engage in such transactions if the loans meet the shared equity loan program requirements for Resale Restriction Programs in FHFA's Duty to Serve Underserved Markets Regulation (Duty to Serve Regulation), without regard to any household income limit.

DATES: The final rule is effective May 13, 2024.

FOR FURTHER INFORMATION CONTACT: Ted Wartell, Associate Director, Office of Housing and Community Investment (OHCI), 202–649–3157, *ted.wartell@fhfa.gov;* or Sara L. Todd, Assistant General Counsel, Office of General Counsel (OGC), 202–649–3527, *sara.todd@fhfa.gov;* Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. These are not toll-free numbers. The mailing address for each contact is: Federal Housing Finance Agency, Fourth Floor, 400 Seventh Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

I. Background

A. Proposed PTFC Rule

On September 26, 2023, FHFA published a Notice of Proposed Rulemaking (proposed PTFC rule) in the

Federal Register to amend FHFA's PTFC Regulation.[1] The proposed PTFC rule proposed adding an exception to the PTFC Regulation's restrictions for loans on properties with PTFCs, and related securities, if the loans meet the shared equity loan program requirements for Resale Restriction Programs, other than the 100 percent of area median income (AMI) limit, in § 1228.34(d)(4)(i)(A) and (d)(4)(ii) of FHFA's Duty to Serve Regulation.[2] Thus, the Enterprises and Banks would be authorized to purchase, invest in, accept as collateral, or otherwise deal in loans on properties with PTFCs, or related securities, if the loans met the requirements for Duty to Serve Resale Restriction Programs, without regard to any household income limit. Relevant discussion from the proposed PTFC rule's preamble is included below.

FHFA received comments on the proposed PTFC rule from Fannie Mae, Freddie Mac, three nonprofit organizations, one trade association, and one individual. The Banks did not submit any comments. The comments are further discussed in Section VI. below.

B. Statutory and Regulatory Background: Enterprises

The Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (Safety and Soundness Act), provides that the Director of FHFA has a duty to ensure that the operations and activities of the Enterprises foster liquid, efficient, competitive, and resilient national housing finance markets.[3] To achieve these goals, the Enterprises purchase residential mortgages that fall within the conforming loan limits established pursuant to 12 U.S.C. 1717 and 12 U.S.C. 1454, and issue guaranteed mortgage-backed securities backed by those loans.

In addition, the Safety and Soundness Act provides generally that the Enterprises ''have an affirmative obligation to facilitate the financing of affordable housing for low- and moderate-income families.'' [4] Section 1129 of the Housing and Economic Recovery Act of 2008 (HERA) amended section 1335 of the Safety and Soundness Act to establish a duty for the Enterprises to serve three specified underserved markets (Duty to Serve) in order to increase the liquidity of mortgage investments and improve the distribution of investment capital available for mortgage financing for certain categories of borrowers in those markets.[5] Specifically, the Enterprises are required to provide leadership in developing loan products and flexible underwriting guidelines to facilitate a secondary market for mortgages on housing for very low-, low-, and moderate-income families for the manufactured housing, affordable housing preservation, and rural housing markets.[6] FHFA's Duty to Serve Regulation,[7] which implements these Duty to Serve statutory requirements, is discussed further below.

C. Statutory and Regulatory Background: Federal Home Loan Banks

The eleven Banks are wholesale financial institutions organized under the Federal Home Loan Bank Act to support housing finance and further affordable housing and community development.[8] The Banks are cooperatives and carry out their mission primarily by providing products and services to their member institutions. Bank members and eligible housing associates (nonmember mortgagee borrowers such as state housing finance agencies) may obtain access to secured loans, known as advances.[9] These must be fully secured by eligible collateral at the time of issuance or renewal, which may include, among other forms of collateral, residential mortgages and mortgage-backed securities.[10] In addition, the Banks issue standby letters of credit on behalf of members and housing associates, which may be secured by residential mortgages and mortgage-backed securities.

Most Banks also offer Acquired Member Assets (AMA) programs, under which they acquire eligible mortgages from participating members and housing associates, subject to parameters set forth in FHFA's AMA regulation.[11] The Banks are also authorized to invest in mortgage-backed securities and other mortgage-related investments meeting applicable requirements.[12] Finally, the Banks may serve as pass-through entities for mortgage loans acquired by another purchaser.

II. PTFC Regulation

FHFA's PTFC Regulation, which was adopted in 2012, prohibits the Enterprises and Banks from purchasing, investing in, or otherwise dealing in any mortgages encumbered by PTFCs, or related securities, and prohibits the Banks from accepting such mortgages or securities as collateral for advances, unless such PTFCs are ''excepted transfer fee covenants.'' [13] Under the PTFC Regulation, the term ''PTFCs'' means obligations that purport to ''run with the land'' in the records of title to real property or to bind current owners of, and successors in title to, such real property, and that obligate a transferee or transferor to pay a private transfer fee upon transfer of the property.[14] A ''private transfer fee'' is defined in the PTFC Regulation as ''a transfer fee, including a charge or payment, imposed by a covenant, restriction, or other similar document and required to be paid in connection with or as a result of a transfer of title to real estate, and payable on a continuing basis each time a property is transferred (except for transfers specifically excepted) for a period of time or indefinitely.'' [15]

In adopting the PTFC Regulation, FHFA was concerned that private transfer fees would: (1) be used to fund purely private continuous streams of income for select market participants, either directly or through securitized investment vehicles; (2) not benefit homeowners or the properties involved; and (3) interfere with accurate determination of property values. Therefore, FHFA concluded that mortgages on properties with PTFCs might impair the safety and soundness of the Enterprises and the Banks that purchase, invest in, or otherwise deal in, or in the case of the Banks, that accept as collateral, such mortgages.[16]

The prohibition in the PTFC Regulation does not apply where the PTFC is an ''excepted transfer fee covenant,'' which is defined in the regulation as a covenant that requires payment to a ''covered association'' and that limits the use of such payment to purposes that provide a ''direct benefit'' to the real property.[17]

[1] 88 FR 65827 (Sept. 26, 2023).

[2] 12 CFR 1282.34(d)(4)(i)(A), (d)(4)(ii).

[3] 12 U.S.C. 4513(a)(1)(B)(ii).

[4] 12 U.S.C. 4501(7).

[5] 12 U.S.C. 4565.

[6] 12 U.S.C. 4565(a). The terms ''very low-income,'' ''low-income,'' and ''moderate-income'' are defined in 12 U.S.C. 4502.

[7] 12 CFR part 1282, subpart C.

[8] *See* 12 U.S.C. 1421 *et seq.*

[9] *See* 12 U.S.C. 1426(a)(4), 1430(a), 1430b.

[10] *See* 12 U.S.C. 1430(a)(3), 1430(b); 12 CFR 1266.7, 1266.17, part 1269.

[11] *See* 12 CFR part 1268.

[12] *See* 12 CFR 1267.3(a)(4)(iv), (v).

[13] 12 CFR 1228.2.

[14] 12 CFR 1228.1.

[15] 12 CFR 1228.1. The definition excludes fees, charges, payments, or other obligations imposed by or payable to the Federal government or a State or local government, or that defray actual costs of the transfer of the property, including transfer of membership in the relevant covered association. The final rule does not modify this exclusion.

[16] *See* 77 FR 15566, 15567 (March 16, 2012).

[17] 12 CFR 1228.1.

III. Interaction Between the PTFC Regulation and the Enterprise Duty To Serve Regulation and Activities

Approximately four years after the adoption of the PTFC Regulation, FHFA adopted the Duty to Serve Regulation, which applies only to the Enterprises.[18] Under the Duty to Serve Regulation, each Enterprise is required to prepare an Underserved Markets Plan (Plan), which is subject to Non-Objection by FHFA, and which describes the specific activities and objectives the Enterprise will undertake over a three-year period to fulfill its Duty to Serve in each underserved market.[19] The regulation identifies specific types of activities that are eligible to receive Duty to Serve credit and that an Enterprise may include in its Plan for each underserved market.[20] An Enterprise may also include additional activities in its Plan, subject to FHFA determination of whether they are eligible to receive Duty to Serve credit.[21]

Under the Duty to Serve Regulation, one of the activities eligible for Duty to Serve credit under the affordable housing preservation market is Enterprise support for shared equity programs for affordable homeownership preservation in the form of resale restriction programs administered by community land trusts, other nonprofit organizations, or state or local governments or instrumentalities (collectively, Resale Restriction Programs).[22] The Duty to Serve Regulation further specifies the following criteria for an eligible Resale Restriction Program:

(a) Provides homeownership opportunities to very low-, low-, or moderate-income households;

(b) Utilizes a ground lease, deed restriction, subordinate loan, or similar legal mechanism that includes provisions stating that the program will keep the home affordable for subsequent very low-, low-, or moderate-income households, the affordability term is at least 30 years after recordation, a resale formula applies that limits the homeowner's proceeds upon resale, and the program administrator or its assignee has a preemptive option to purchase the homeownership unit from the homeowner at resale; and

(c) Supports homebuyers and homeowners to promote sustainable homeownership, including reviewing and pre-approving refinances and home equity lines of credit.[23]

The proposed PTFC rule referred to the very low-, low-, and moderate-income household income limits in these Duty to Serve regulatory provisions as the ''100 percent of area median income limit,'' which is the definition of ''moderate-income'' in the Safety and Soundness Act and the Duty to Serve Regulation. The definitions of ''very low-income'' (50 percent of AMI) and ''low-income'' (80 percent of AMI) are subsumed within the definition of ''moderate-income.'' [24]

The preamble to the 2015 proposed Duty to Serve rule noted that many shared equity loan programs allow the program sponsors (also called administrators) to charge modest fees that cover the cost of operating the program.[25] However, the preamble to the final Duty to Serve rule did not reiterate this discussion of fees, nor did its regulatory text include a reference to fees.[26] The final Duty to Serve rule also did not refer to or amend the PTFC Regulation to provide an exception to the restriction on PTFCs for loans that meet Resale Restriction Program requirements in the Duty to Serve Regulation.

Prior to FHFA's issuance of the proposed PTFC rule, between 2018 (the first year of Duty to Serve program implementation) and 2022, the Enterprises, collectively, purchased more than 800 shared equity loans that met Duty to Serve criteria. Both Enterprises' 2022–2024 Duty to Serve Plans include plans to purchase shared equity loans under Resale Restriction Programs in each of the Plan years.

During the Enterprises' efforts to implement the shared equity loan objectives in their current Duty to Serve Plans, the Enterprises reviewed model organizational documents that were proposed to be used as templates by Resale Restriction Programs. In preparing to establish approved templates, the Enterprises determined that, while Resale Restriction Programs using the templates would meet the criteria for Resale Restriction Programs in the Duty to Serve Regulation, except for the household income limit, the programs' possible inclusion of PTFC payment requirements could cause any loans issued under the terms of the model organizational documents to be ineligible for purchase by the Enterprises because of the PTFC Regulation's limitations. The Enterprises also realized that loans they purchased previously under many of the Resale Restriction Programs are secured by properties encumbered by PTFCs that fall within the PTFC Regulation's prohibition because they bind current owners and successors to pay a fee to the program administrator (often a community land trust) on a continuing basis each time the property is transferred, but those PTFCs do not meet the PTFC Regulation's definition of an ''excepted transfer fee covenant.'' [27]

IV. Regulatory Waiver of § 1228.2 for the Enterprises—Proposed § 1228.1

In response to the Enterprises' identification of PTFCs in shared equity loans under Resale Restriction Programs that otherwise would be eligible for purchase and qualify for Duty to Serve credit, FHFA reviewed these types of loans and determined that the private transfer fees in these programs are not the types of fees that prompted the concern underlying the PTFC Regulation. Unlike fees paid to the select market participants that concerned FHFA when the PTFC Regulation was adopted, the fees in Resale Restriction Programs reimburse the program administrators, which are typically community land trusts, nonprofits, or local governments, for their ongoing operating expenses related to the purchase and sale of affordable homes under the program. The fees are not used as a method to provide a continuous income stream to the program administrators with no continuing affordable housing-related services provided. For example, fees in Resale Restriction Programs may be used to pay for: maintaining a list of, and qualifying, prospective program-eligible homebuyers; providing seller representation and outreach to prospective buyers; ensuring that repairs are incorporated into the sale transaction; providing potential homebuyers with homeownership counseling or similar education; exercising the program administrator's option to purchase the home if the

[18] 12 CFR part 1282, subpart C; 81 FR 96242 (Dec. 29, 2016).

[19] 12 CFR 1282.32(a), (b).

[20] *See* 12 CFR 1282.33(c) for eligible activities in the manufactured housing market; 12 CFR 1282.34(c), (d) for eligible activities in the affordable housing preservation market; and 12 CFR 1282.35(c) for eligible activities in the rural housing market.

[21] 12 CFR 1282.32(d)(2).

[22] 12 CFR 1282.34(d)(4)(i)(A).

[23] 12 CFR 1282.34(d)(4)(ii).

[24] 12 CFR 1282.1(b); 12 U.S.C. 4502(14), (16), (24).

[25] 80 FR 79181, 79203 (Dec. 18, 2015).

[26] 81 FR 96294 (Dec. 29, 2016); 12 CFR 1282.34(d)(4).

[27] The fees or payments are used by the program administrator to pay for its operating costs, including costs of enforcing the long-term affordability requirements. They are not limited to costs and activities that are specific to the ''burdened community'' in which the subject property is located, nor are they otherwise required to be used for the purpose of providing a ''direct benefit'' to the property (as these quoted terms are defined in the PTFC Regulation). *See* 12 CFR 1228.1.

homeowner defaults on the first lien or the affordability restriction; enforcing the long-term affordability requirements (such as calculating the maximum resale price according to the resale formula); and executing legal documents with subsequent homebuyers.

The Enterprises and other practitioners familiar with shared equity programs also provided input that these programs typically set income limits up to 140 percent of AMI, which is above the Duty to Serve household income limit of 100 percent of AMI, especially in communities where housing costs are high relative to incomes. Fannie Mae also noted that limiting eligibility under the PTFC Regulation to loans that meet the Duty to Serve household income limit would require lenders and shared equity program administrators to use a differentiated approach with borrowers above and below the income limit. Further, it would require lenders to review each loan to ensure eligibility for purchase by the Enterprises. FHFA finds these points persuasive, and agrees that the burden and potential deterrent effect of this differentiated approach and additional review would undermine the objective of standardizing the shared equity homeownership market and increasing the number of Enterprise shared equity loan purchases under the Duty to Serve program.

Accordingly, FHFA issued a temporary prospective waiver of the private transfer fee restrictions in § 1228.2 of the PTFC Regulation for Enterprise purchases or securitizations of shared equity loans on properties with PTFCs that meet the shared equity loan program criteria for Resale Restriction Programs, other than the Duty to Serve 100 percent of AMI limit, in 12 CFR 1282.34(d)(4)(i)(A) and (d)(4)(ii) of the Duty to Serve Regulation, through the remaining term of the Enterprises' current 2022–2024 Duty to Serve Plans, *i.e.,* through December 31, 2024.

The waiver also included a retrospective component that waived the restrictions in the PTFC Regulation for shared equity loans on properties with private transfer fees purchased or securitized by the Enterprises with note dates prior to July 1, 2023, regardless of whether the loans met the Duty to Serve shared equity loan program criteria for Resale Restriction Program loans that were in effect when the loans were purchased.

Finally, the waiver provided notice of FHFA's intention to promptly engage in notice-and-comment rulemaking to propose amending the PTFC Regulation to codify the waiver provisions. To implement that intent, FHFA published the proposed PTFC rule referenced in Section I. above, which proposed to amend the definition of ''excepted transfer fee covenant'' in § 1228.1 of the PTFC Regulation to add as an exception a PTFC that encumbers a property for which a shared equity loan meets the requirements of a Duty to Serve Resale Restriction Program, other than the 100 percent of AMI limit, in 12 CFR 1282.34(d)(4)(i)(A) and (d)(4)(ii).

V. Interaction Between the PTFC Regulation and the Banks' Activities—Proposed § 1228.1

As noted above, the PTFC Regulation also prohibits the Banks from purchasing, investing in, or otherwise dealing in mortgages on properties encumbered by PTFCs, or related securities, and prohibits the Banks from accepting such mortgages or securities as collateral for advances, subject to the exceptions in the regulation.[28] The Banks have indicated that, to their knowledge, they have not purchased, or accepted as collateral, any shared equity loans. The same considerations discussed above for the Enterprises regarding differences in the uses of fees payable at resale to administrators of Resale Restriction Programs and the fees that FHFA was concerned about when the PTFC Regulation was adopted, also apply to the Banks. However, because the waiver for the Enterprises derived from their activities under the Duty to Serve Regulation (which does not apply to the Banks), the waiver did not address activities of the Banks with respect to shared equity loans. The Banks might decide in the future to purchase, invest in, accept as collateral, or otherwise deal in shared equity loans, or related securities, under Resale Restriction Programs, to facilitate increased liquidity for affordable homeownership. Therefore, FHFA proposed in the proposed PTFC rule that the exception added in § 1228.1 for the Enterprises also apply to the Banks.

VI. Public Comments Received on the Proposed PTFC Rule

FHFA requested feedback on specific questions posed in the proposed PTFC rule's preamble, each of which is discussed below. FHFA received comments on the proposed PTFC rule from Fannie Mae, Freddie Mac, three nonprofit organizations that are active in the shared equity housing industry, a home builders trade association, and an individual. None of the Banks submitted comments. FHFA has reviewed and considered all of the comments, which overwhelmingly supported the proposed PTFC rule.

The individual commenter expressed general disagreement with government regulation of the mortgage market and opposed the proposed PTFC rule on that basis. For the reasons described above, FHFA, as regulator of the Enterprises and the Banks, is proceeding with this rulemaking because FHFA believes the original basis for the PTFC Regulation continues to support the restrictions therein and there is a reasonable basis to adopt the proposed amendments.

The specific questions that FHFA invited commenters to address were as follows:

1. Should the proposed PTFC rule apply to the Banks in addition to the Enterprises? Do differences between the Banks and the Enterprises warrant additional or other revisions to the proposed PTFC rule as it relates to the Banks?

The home builders trade association and one nonprofit organization supported applying the provisions in the proposed PTFC rule to the Banks in addition to the Enterprises. These commenters stated that this broad application would remove barriers that might prevent the Banks from expanding their activities to include shared equity homeownership, including investing in shared equity loans or related securities, or accepting these loans as collateral. The other commenters did not address this question.

2. Should all of the Duty to Serve Resale Restriction Program criteria, including the 100 percent of AMI limit, apply to the determination of whether a mortgage loan that is subject to PTFCs, or a related security, is eligible for purchase, investment, otherwise dealing in, or acceptance as collateral by the Banks and Enterprises? If not, which of those specific criteria should apply?

3. Should criteria other than the Duty to Serve Resale Restriction Program criteria (such as an income limit different from 100 percent of AMI), apply to the determination of eligibility?

Two of the nonprofit organizations and both Enterprises supported the proposed approach—applying the Duty to Serve Resale Restriction Program criteria other than the Duty to Serve household income limit—to the determination of whether a mortgage loan that is subject to PTFCs, or a related security, is eligible for purchase, investment, otherwise dealing in, or acceptance as collateral by the Banks and Enterprises. The third nonprofit organization stated that it did not have an opinion on whether to apply the Duty to Serve household income limit.

[28] 12 CFR 1228.2.

The home builders trade association generally supported applying the proposed PTFC rule to the Banks, which FHFA construes as support for not applying the Duty to Serve household income limit.

The two nonprofit organizations that supported the proposed approach noted that market conditions are leading many shared equity programs to serve homebuyers with incomes that are higher than the Duty to Serve household income limit. These commenters stated that applying a household income limit would unnecessarily limit flexibility and restrict secondary market access for lenders, shared equity homeownership programs, and homebuyers. One of these nonprofit organizations encouraged FHFA to allow the Enterprises to advance standardization in the shared equity homeownership market, including for shared equity loans to higher-income homebuyers, whose loans would be eligible for purchase or investment by an Enterprise or Bank even though they are ineligible for Duty to Serve credit.

Fannie Mae commented that the proposed PTFC rule would clarify how the Enterprises can continue to provide liquidity in the shared equity homeownership market, and Freddie Mac commented that the proposed PTFC rule would contribute to its ability to increase access to credit for this underserved market. Fannie Mae suggested that applying a household income limit would require lenders and shared equity programs to use different approaches with borrowers above and below the limit, which could result in additional cost burdens for borrowers below the limit. FHFA finds this an additional persuasive reason to not apply a household income limit.

Fannie Mae suggested a technical edit that it stated would better align the language in § 1228.1 of the proposed PTFC rule with the language in the Duty to Serve Regulation, making it easier for lenders and others in the housing industry to interpret and apply the language. Specifically, Fannie Mae suggested that the proposed PTFC rule's reference to ''the Duty to Serve 100 percent of area median income limit'' be changed to the Duty to Serve ''provisions relating to very low-, low- and moderate-income families and households'' (the individual income limit components). FHFA agrees that greater clarity could be provided regarding these references and has adopted a different, more straightforward technical change to the language in the final rule. Specifically, rather than refer to the ''100 percent of area median income limit,'' the final rule states that ''no household income limit shall apply.'' (Because no household income limit will apply, it is unnecessary to add references to the individual income limit components.)

4. Should criteria in addition to the Duty to Serve Resale Restriction Program criteria apply to the determination of eligibility?

Fannie Mae and one of the nonprofit organizations opposed applying criteria in addition to the Duty to Serve Resale Restriction Program criteria when determining eligibility of loans for purchase by the Enterprises, with the nonprofit organization stating that the Duty to Serve criteria have worked well to date. The other commenters did not address this question.

VII. Limitation on Applicability—Proposed § 1228.3

The proposed PTFC rule proposed removing the prospective application and effective date in § 1228.3 of the PTFC Regulation. Section 1228.3 currently includes a ''grandfather'' provision for mortgages on certain properties encumbered by PTFCs if those PTFCs were created pursuant to an agreement entered into before the July 16, 2012 effective date of the PTFC Regulation. The transitional provision is no longer necessary because the Enterprises and the Banks have been operating under the terms of the PTFC Regulation since July 16, 2012, and the Enterprises subsequently have been operating under the terms of the regulatory waiver since July 1, 2023. The prospective application date (*i.e.,* the effective date) of this final rule is May 13, 2024. This date precedes December 31, 2024, which is the conclusion of the 2022–2024 Duty to Serve Plan cycle and the date on which the temporary prospective component of the waiver will expire.

The proposed PTFC rule also proposed to revise § 1228.3 to include the retrospective component of the waiver, by allowing the Enterprises to retain in their portfolios shared equity loans on properties with private transfer fees that were purchased or securitized by the Enterprises with note dates prior to the effective date of the waiver (July 1, 2023), regardless of whether the loans met the Duty to Serve shared equity loan program criteria for Resale Restriction Programs in 12 CFR 1282.34(d)(4)(i)(A) and (d)(4)(ii).

No comments were received on the proposed revisions to § 1228.3. The final rule adopts the proposed revisions to § 1228.3 with technical changes to improve clarity regarding the intent of the provisions. Specifically, the final rule adds the word ''promissory'' before ''note'' to clarify that the limitation on applicability applies to promissory notes and not to other types of notes. In addition, the phrase ''that were purchased or securitized by the Enterprises'' is removed in the final rule to make clear that the sentence applies broadly to all of the activities of both the Enterprises and the Banks encompassed in § 1228.2. In other words, part 1228 is inapplicable not only to purchases and securitizations of shared equity loans, or related securities, with promissory note dates prior to July 1, 2023, but also to investing in, accepting as collateral, or otherwise dealing in such loans or related securities.

VIII. Final Rule

For the reasons discussed above and after considering the comments received on the proposed PTFC rule, which overwhelmingly supported the proposed PTFC rule, FHFA is adopting the proposed PTFC rule as a final rule with the change to the household income limit language in § 1228.1, and the technical changes in § 1228.3, as summarized below.

A. § 1228.1—Definition of ''Excepted Transfer Fee Covenant''

The final rule revises the definition of ''excepted transfer fee covenant'' in § 1228.1 to add an exception, in new paragraph (2), to the regulation's restrictions on loans on properties with PTFCs, and related securities, if the PTFC requires payment of a private transfer fee under a program meeting the Duty to Serve shared equity loan program criteria for Resale Restriction Programs in 12 CFR 1282.34(d)(4)(i)(A) and (d)(4)(ii), except that no household income limit shall apply.

B. § 1228.3—Limitation on Applicability

The final rule revises § 1228.3 by removing the transitional provision with prospective application and effective dates that are long past, and providing instead that this part is not applicable to shared equity loans, or related securities, with promissory note dates prior to July 1, 2023, regardless of whether the loans met the Duty to Serve shared equity loan program criteria for Resale Restriction Programs in 12 CFR 1282.34(d)(4)(i)(A) and (d)(4)(ii).

IX. Paperwork Reduction Act

The final rule does not contain any information collection requirement. Thus, it does not require approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Therefore, FHFA has not submitted any information to OMB for review.

X. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. FHFA need not undertake such an analysis if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the final rule under the Regulatory Flexibility Act and FHFA certifies that the final rule will not have a significant economic impact on a substantial number of small entities because the final rule applies only to Fannie Mae, Freddie Mac, and the Banks, which are not small entities for purposes of the Regulatory Flexibility Act.

XI. Congressional Review Act

In accordance with the Congressional Review Act (5 U.S.C. 801 *et seq.*), FHFA has determined that this final rule is a major rule and has verified this determination with OMB.

XII. Consideration of Differences Between the Banks and the Enterprises

When promulgating regulations relating to the Banks, section 1313(f) of the Safety and Soundness Act requires the Director of FHFA to consider the differences between the Banks and the Enterprises with respect to: the Banks' cooperative ownership structure; mission of providing liquidity to members and housing associates; affordable housing and community development mission; capital structure; and joint and several liability. In the proposed PTFC rule's preamble, FHFA requested comments regarding whether differences related to those factors should result in any additional or other revisions to the proposed PTFC rule. No commenter on the proposed PTFC rule supported amending the PTFC Regulation to apply different criteria to the Banks or the Enterprises.

In preparing this final rule, FHFA considered the differences between the Banks and the Enterprises as they relate to the above factors and the lack of comments supporting applying different criteria to the Banks or the Enterprises. FHFA determined that the final rule is appropriate as it would have no impact on four of the five factors and could have a modest, positive impact on the fifth factor—the mission of providing liquidity to Bank members and housing associates.

List of Subjects in 12 CFR Part 1228

Banks, Banking, Condominiums, Cooperatives, Federal Home Loan Banks, Government-sponsored enterprises, Investments, Loan programs – housing and community development, Low and moderate income housing, Mortgages, Nonprofit organizations, Real property acquisition, Securities.

For the reasons stated in the preamble, and under the authority of 12 U.S.C. 4526, FHFA amends part 1228 of chapter XII of title 12 of the Code of Federal Regulations as follows:

PART 1228—RESTRICTIONS ON THE ACQUISITION OF, OR TAKING SECURITY INTERESTS IN, MORTGAGES ON PROPERTIES ENCUMBERED BY CERTAIN PRIVATE TRANSFER FEE COVENANTS AND RELATED SECURITIES

■ 1. The authority citation for part 1228 is revised to read as follows:

Authority: 12 U.S.C. 4511, 4513, 4526, 4565, 4616, 4617, 4631.

■ 2. Amend § 1228.1 by revising the definition of ''Excepted transfer fee covenant'' to read as follows:

§ 1228.1 Definitions.

* * * * *

Excepted transfer fee covenant means a private transfer fee covenant that:

(1) Requires payment of a private transfer fee to a covered association and limits the use of such transfer fees exclusively to purposes which provide a direct benefit to the real property encumbered by the private transfer fee covenants; or

(2) Requires payment of a private transfer fee under a program meeting the Duty to Serve shared equity loan program criteria for resale restriction programs in § 1282.34(d)(4)(i)(A) and (d)(4)(ii) of this chapter, except that no household income limit shall apply.

* * * * *

■ 3. Revise § 1228.3 to read as follows:

§ 1228.3 Limitation on applicability.

This part is not applicable to shared equity loans, or related securities, with promissory note dates prior to July 1, 2023, regardless of whether the loans met the Duty to Serve shared equity loan program criteria for resale restriction programs in § 1282.34(d)(4)(i)(A) and (d)(4)(ii) of this chapter.

Sandra L. Thompson,

Director, Federal Housing Finance Agency.

[FR Doc. 2024–05194 Filed 3–11–24; 8:45 am]

BILLING CODE 8070–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 130

RIN 3245–AE05

Small Business Development Centers; Correction

AGENCY: U.S. Small Business Administration.

ACTION: Final rule; correcting amendments.

SUMMARY: The U.S. Small Business Administration (SBA or the Agency) is correcting a final rule published in the **Federal Register** on November 7, 2023. The rule updated the regulations for the Small Business Development Centers Program (the SBDC Program or the Program).

DATES: This correction is effective March 12, 2024.

FOR FURTHER INFORMATION CONTACT: Rachel Karton, Program Manager for the SBDC Program, at 202–205–6766 or *rachel.newman-karton@sba.gov.*

SUPPLEMENTARY INFORMATION: In a final rule published on November 7, 2023 (88 FR 76625), SBA incorporated the Uniform Guidance at 2 CFR part 200 on receiving and using Federal awards; made various revisions to align the regulations with the text of the SBDC statute; and adopted the proposed rule with changes from the comments received in response to the publication of the NPRM. This correction to the final rule makes three clarifications. First, it clarifies the basis on which the Administrator may make an exception to the client privacy restriction of § 130.380. Second, it corrects the definition of ''Overmatched amount'' in § 130.110 to match the guidelines provided in § 130.450(g). Finally, it revises the last sentence in § 130.450(g)(3).

List of Subjects in 13 CFR Part 130

Grant programs—business, Small businesses, Technical assistance.

Accordingly, the Small Business Administration amends 13 CFR part 130 by making the following correcting amendments:

PART 130—SMALL BUSINESS DEVELOPMENT CENTERS

■ 1. The authority citation for part 130 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), 648, and 648 note.

■ 2. Amend § 130.110 by revising the definition of ''Overmatched amount'' to read as follows:

§ 130.110 Definitions.

* * * * *

Overmatched amount. Overmatched amounts are those which are derived from eligible matching sources; are reasonable, allowable, and allocable to the SBDC program; are over and above the minimum match required to the federal expenditures; and are included on the required SBDC financial reporting to SBA for the project period.

* * * * *

■ 3. Amend § 130.380 by revising paragraph (a)(2) to read as follows:

§ 130.380 Client privacy.

(a) * * *

(2) The Administrator considers such a disclosure to be necessary for the purpose of conducting a financial audit of a small business development center, not including those required under § 130.830; or

* * * * *

■ 4. Amend § 130.450 by revising the last sentence in paragraph (g)(3) to read as follows:

§ 130.450 Matching funds.

* * * * *

(g) * * *

(3) * * * Such offsetting funds may be applied to Federal or matching accounts.

* * * * *

Mark Madrid,

Associate Administrator, Office of Entrepreneurial Development.

[FR Doc. 2024–05146 Filed 3–11–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2141; Project Identifier MCAI–2023–00689–T; Amendment 39–22672; AD 2024–03–03]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A350–941 and –1041 airplanes. This AD was prompted by reports of corrosion on lavatory floor fittings at various locations. This AD requires repetitive general visual inspections of the affected parts, applicable corrective actions, and reporting of the inspection results, 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 April 16, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 16, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2141; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material incorporated by reference in this AD, 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 at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–2141.

FOR FURTHER INFORMATION CONTACT: Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7317; email *dat.v.le@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 SAS Model A350–941 and –1041 airplanes. The NPRM published in the **Federal Register** on November 3, 2023 (88 FR 75520). The NPRM was prompted by AD 2023–0102, dated May 17, 2023, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2023–0102) (also referred to as the MCAI). The MCAI states there are reports of corrosion on lavatory floor fittings at various locations on Model A350 airplanes.

In the NPRM, the FAA proposed to require repetitive general visual inspections of the affected parts, applicable corrective actions, and reporting of inspection results, as specified in EASA AD 2023–0102. The FAA is issuing this AD to address the corrosion, which could lead to lavatory module detachment, with consequent injury to cabin crew and passengers, and possibly result in reduced evacuation capacity from the airplane in case of an emergency.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–2141.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI 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 this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0102 specifies procedures for repetitive general visual inspections for corrosion and other damage (including cracks, pitting, discoloration, and dents) of the affected lavatory floor fittings and, depending on findings, corrective actions including repair or replacement. EASA AD 2023–0102 also requires reporting of the inspection results after each inspection.

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

Interim Action

The FAA considers this AD an interim action. If final action is later identified, the FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this AD would affect 32 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$0	$170	$5,440

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × $85 per hour = $255	$10	$265

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

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–03–03 Airbus SAS: Amendment 39–22672; Docket No. FAA–2023–2141; Project Identifier MCAI–2023–00689–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 16, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by reports of corrosion on lavatory floor fittings at various

locations on Model A350 airplanes. The unsafe condition, if not addressed, could lead to lavatory module detachment, with consequent injury to cabin crew and passengers, and possibly result in reduced evacuation capacity from the airplane in case of an emergency.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0102, dated May 17, 2023 (EASA AD 2023–0102).

(h) Exceptions to EASA AD 2023–0102

(1) Where EASA AD 2023–0102 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0102.

(3) Paragraph (4) of EASA AD 2023–0102 specifies to report inspection results to Airbus within a certain compliance time. For this AD, report inspection results at the applicable time specified in paragraph (h)(3)(i) or (ii) of this AD.

(i) For each inspection done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) For any inspection done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(4) Where paragraph (2) of EASA AD 2023–0102 specifies ''any discrepancy, as defined in the SB, is detected,'' this AD requires replacing those words with ''any corrosion and other damage is detected.''

(i) No Requirement for Return of Parts

Although the service information referenced in EASA AD 2023–0102 specifies to return parts to the manufacturer, this AD does not include that requirement.

(j) 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 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.* 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.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7317; email *dat.v.le@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0102, dated May 17, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0102, 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 EASA AD on the EASA website at *ad.easa.europa.eu.*

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

(5) You may view this 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-locationsoremailfr.inspection@nara.gov.*

Issued on February 6, 2024.

Victor Wicklund,

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

[FR Doc. 2024–05190 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2001; Project Identifier MCAI–2023–00666–T; Amendment 39–22676; AD 2024–03–06]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–20–13, which applied to certain Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes. AD 2021–20–13 required repetitive lubrication and repetitive detailed visual inspections (DVI) and non-destructive test (NDT) inspections of the main landing gear (MLG) shock strut lower pins, and replacement if necessary. This AD continues to require the lubrication and inspections specified in AD 2021–20–13 until the MLG shock strut assembly is modified by replacing the trailing arm bushing and installing new dynamic joint components. This AD was prompted by a new design solution for this potential failure of the shock strut lower pin. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 16, 2024.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 16, 2024.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of November 18, 2021 (86 FR 57033, October 14, 2021).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2001; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For service information identified in this final rule, contact Bombardier,

Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

• 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–2023–2001.

FOR FURTHER INFORMATION CONTACT: Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–20–13, Amendment 39–21751 (86 FR 57033, October 14, 2021) (AD 2021–20–13). AD 2021–20–13 applied to certain Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes. AD 2021–20–13 required repetitive lubrication and repetitive DVI and NDT inspections of the MLG shock strut lower pins, and replacement if necessary. The FAA issued AD 2021–20–13 to correct an unsafe condition identified as cracking of the MLG shock strut lower pin part number 19146–3.

The NPRM published in the **Federal Register** on October 25, 2023 (88 FR 73265). The NPRM was prompted by AD CF–2023–32, dated May 9, 2023, issued by Transport Canada, which is the aviation authority for Canada (Transport Canada AD CF–2023–32) (also referred to as the MCAI). The MCAI states there is a new design solution for this potential failure of the shock strut lower pin, which involves replacing the training arm bushings at the attachment and reassembly of the MLG shock strut assembly to training arm assembly joint with new dynamic joint components. As a result, the MCAI requires this new design as terminating action for the requirements of Transport Canada AD CF–2020–54R1.

In the NPRM, the FAA proposed to continue to require the lubrication and inspections specified in AD 2021–20–13 until the MLG shock strut assembly is modified by replacing the trailing arm bushing and installing new dynamic joint components. The FAA is issuing this AD to address cracking of the MLG shock strut lower pin. The unsafe condition, if not addressed, could result in structural failure of one or both MLG.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–2001.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters, including Executive Jet Management, Inc., NetJets, and Boeing. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Update the Service Information to the Latest Revision and Provide Credit

Executive Jet Management, Inc. NetJets, and Boeing requested the FAA revise the proposed AD to allow using Bombardier Service Bulletin 604–32–031 Revision 01, dated March 17, 2023; Bombardier Service Bulletin 605–32–008 Revision 01, dated March 17, 2023; and Bombardier Service Bulletin 650–32–005 Revision 01, dated March 17, 2023. NetJets also requested that the proposed AD be revised to add credit for using the original issues of the service information.

The FAA agrees to update this final rule to reference Bombardier Service Bulletin 604–32–031 Revision 01, dated March 17, 2023; Bombardier Service Bulletin 605–32–008 Revision 01, dated March 17, 2023; and Bombardier Service Bulletin 650–32–005 Revision 01, dated March 17, 2023, which include minor changes that do not affect the substantive requirements proposed in the NPRM. The FAA has revised this AD to reflect the updated service bulletins. The FAA has also added paragraph (n) of this AD to provide credit for the original issues of the applicable service bulletins, and redesignated subsequent paragraphs accordingly.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following Bombardier service information:

• Service Bulletin 604–32–031, Revision 01, dated March 17, 2023.

• Service Bulletin 605–32–008, Revision 01, dated March 17, 2023.

• Service Bulletin 650–32–005, Revision 01, dated March 17, 2023.

This service information contains procedures for disassembling the left- and right-hand MLG shock strut and trailing arm joint, replacing the trailing arm bushings at the attachment, and re-assembling the joint with new dynamic joint components. These documents are distinct since they apply to different airplane configurations.

This AD also requires the following Bombardier service information, which the Director of the Federal Register approved for incorporation by reference as of November 18, 2021 (86 FR 57033, October 14, 2021):

• Service Bulletin 604–32–030, dated June 30, 2020.

• Service Bulletin 605–32–007, dated June 30, 2020.

• Service Bulletin 650–32–004, dated June 30, 2020.

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

Costs of Compliance

The FAA estimates that this AD affects 433 airplanes of U.S. registry.

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Lubrication and inspections (retained actions from AD 2021–20–13).	7 work-hours × $85 per hour = $595	$0	$595 per cycle	$257,635 per cycle.
Modification and testing (new actions)	9 work-hours × $85 per hour = $765	2,435	$3,200	$1,385,600.

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

ESTIMATED COSTS OF ON-CONDITION REPLACEMENT

Labor cost	Parts cost	Cost per product
6 work-hours × $85 per hour = $510	$2,435	$2,945

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2021–20–13, Amendment 39–21751 (86 FR 57033, October 14, 2021); and

■ b. Adding the following new Airworthiness Directive:

2024–03–06 Bombardier, Inc: Amendment 39–22676; Docket No. FAA–2023–2001; Project Identifier MCAI–2023–00666–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 16, 2024.

(b) Affected ADs

This AD replaces AD 2021–20–13, Amendment 39–21751 (86 FR 57033, October 14, 2021) (AD 2021–20–13).

(c) Applicability

This AD applies to Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes, serial numbers (S/N) 5301 through 5665 inclusive, 5701 through 5988 inclusive, and 6050 through 6188 inclusive, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by reports of cracking of the main landing gear (MLG) shock strut lower pin. The FAA is issuing this AD to address cracking of the MLG shock strut lower pin. The unsafe condition, if not addressed, could result in structural failure of one or both MLG.

(f) Compliance

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

(g) Retained Repetitive Lubrication, With Revised Applicability

This paragraph restates the requirements of paragraph (g) of AD 2021–20–13, with revised applicability. Within 200 flight hours (FH) or 12 months after November 18, 2021 (the effective date of AD 2021–20–13), whichever occurs first, lubricate the left-hand (LH) and right-hand (RH) MLG shock strut lower pins having part number (P/N) 19146–3, in accordance with paragraph 2.B., ''Part A,'' of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (g)(1) through (3) of this AD. Repeat thereafter at intervals not to exceed 200 FH or 12 months, whichever occurs first.

(1) For airplanes having S/N 5301 through 5665 inclusive: Bombardier Service Bulletin 604–32–030, dated June 30, 2020.

(2) For airplanes having S/N 5701 through 5988 inclusive: Bombardier Service Bulletin 605–32–007, dated June 30, 2020.

(3) For airplanes having S/N 6050 through 6188 inclusive: Bombardier Service Bulletin 650–32–004, dated June 30, 2020.

(h) Retained Detailed Visual Inspections (DVI), With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2021–20–13, with no changes. At the applicable compliance time specified in paragraphs (h)(1) through (3) of this AD, perform the DVI for cracking and damage of the LH and RH MLG shock strut lower pins having part number (P/N) 19146–3, in accordance with paragraph 2.C., ''Part B,'' of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (g)(1) through (3) of this AD.

Repeat thereafter at intervals not to exceed 400 FH or 24 months, whichever occurs first. If the DVI coincides with a non-destructive testing (NDT) inspection required by paragraph (i) of this AD, the NDT inspection supersedes the DVI for that interval only. If the accumulated flight cycles (FC) of the MLG shock strut lower pin are not known, use the related MLG assembly accumulated FC to determine when to accomplish the actions required by this paragraph.

(1) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2021 (the effective date of AD 2021–20–13) and on which an MLG shock strut lower pin has accumulated fewer than 600 total FC on the pin as of November 18, 2021: Before the accumulation of 750 total FC on the pin.

(2) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2021 (the effective date of AD 2021–20–13) and on which an MLG shock strut lower pin has accumulated 600 total FC or more on the pin as of November 18, 2021: Within 150 FC after November 18, 2021.

(3) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after November 18, 2021 (the effective date of AD 2021–20–13): Before the accumulation of 750 total FC.

(i) Retained NDT Inspection, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2021–20–13, with no changes. At the applicable compliance time specified in paragraphs (i)(1) through (4) of this AD: Perform the NDT inspection for cracking and damage of the LH and RH MLG shock strut lower pins having P/N 19146–3, in accordance with paragraph 2.D., ''Part C,'' of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (g)(1) through (3) of this AD. Repeat thereafter at intervals not to exceed 900 FC. If the accumulated FC of the MLG shock strut lower pin is not known, use the related MLG assembly accumulated FC to determine when to accomplish the actions required by this paragraph.

(1) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2021 (the effective date of AD 2021–20–13) and on which an MLG shock strut lower pin has accumulated fewer than 1,200 total FC on the pin as of November 18, 2021: Before the accumulation of 1,500 total FC on the pin.

(2) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2021 (the effective date of AD 2021–20–13) and on which an MLG shock strut lower pin has accumulated 1,200 total FC or more but fewer than 2,000 total FC on the pin as of November 18, 2021: Within 300 FC after November 18, 2021, or before the accumulation of 2,200 total FC on the pin, whichever occurs first.

(3) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2021 (the effective date of AD 2021–20–13) and on which an MLG shock strut lower pin has accumulated 2,000 total FC or more on the pin as of November 18, 2021: Within 200 FC after November 18, 2021.

(4) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after November 18, 2021 (the effective date of AD 2021–20–13): Before the accumulation of 1,500 total FC.

(j) Retained Replacement, With No Changes

This paragraph restates the requirements of paragraph (j) of AD 2021–20–13, with no changes. If, during any inspection required by this AD, any crack or damage of the MLG shock strut lower pin is detected, before further flight, replace the affected MLG shock strut lower pin with a new part in accordance with paragraph 2.E., ''Part D,'' of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (g)(1) through (3) of this AD.

(k) New Requirement of This AD: Modification

Within 60 months from the effective date of this AD, modify the LH and RH MLG assembly in accordance with paragraph 2.B. of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (k)(1) through (3) of this AD.

(1) For airplanes having S/N 5301 through 5665 inclusive: Bombardier Service Bulletin 604–32–031, Revision 01, dated March 17, 2023.

(2) For airplanes having S/N 5701 through 5988 inclusive: Bombardier Service Bulletin 605–32–008, Revision 01, dated March 17, 2023.

(3) For airplanes having S/N 6050 through 6188 inclusive: Bombardier Service Bulletin 650–32–005, Revision 01, dated March 17, 2023.

(l) New Requirement of the AD: Testing

Before further flight after completing the actions required by paragraph (k) of this AD, perform the testing of the MLG shock strut assembly to trailing arm assembly joint in accordance with paragraph 2.C. of the Accomplishment Instructions of the applicable service bulletin, as specified in paragraphs (k)(1) through (3) of this AD.

(m) Terminating Action

Modifying and testing an airplane as required by paragraphs (k) and (l) of this AD terminates the initial and repetitive lubrication and inspections required by paragraphs (g), (h), and (i) of this AD for that airplane.

(n) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (k) and (l) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 604–32–031, dated December 29, 2022; Bombardier Service Bulletin 605–32–008, dated December 29, 2022; or Bombardier Service Bulletin 650–32–005, dated December 29, 2022.

(o) Additional AD Provisions

(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 (p)(2) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov*. If mailing information, also submit information by email. 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 Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(p) Additional Information

(1) Refer to Transport Canada AD CF–2023–32, dated May 9, 2023, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–2001.

(2) For more information about this AD, contact Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov*.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (q)(5) and (6) of this AD.

(q) 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 April 16, 2024.

(i) Bombardier Service Bulletin 604–32–031, Revision 01, dated March 17, 2023.

(ii) Bombardier Service Bulletin 605–32–008, Revision 01, dated March 17, 2023.

(iii) Bombardier Service Bulletin 650–32–005, Revision 01, dated March 17, 2023.

(4) The following service information was approved for IBR on November 18, 2021 (86 FR 57033, October 14, 2021).

(i) Bombardier Service Bulletin 604–32–030, dated June 30, 2020.

(ii) Bombardier Service Bulletin 605–32–007, dated June 30, 2020.

(iii) Bombardier Service Bulletin 650–32–004, dated June 30, 2020.

(5) For service information identified in this AD, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–

866–538–1247 or direct-dial telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

(6) 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.

(7) 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-locationsoremailfr.inspection@nara.gov.*

Issued on February 7, 2024.

Victor Wicklund,

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

[FR Doc. 2024–05191 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2230; Project Identifier MCAI–2023–00861–T; Amendment 39–22677; AD 2024–03–07]

RIN 2120–AA64

Airworthiness Directives; Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftahrt GmbH) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Deutsche Aircraft GmbH Model 328–100 and 328–300 airplanes. This AD was prompted by operator reports of worn and ruptured bonding straps inside the feeder wing tanks and in both outer and inner wing tanks. This AD requires a one-time detailed inspection of each affected part, and applicable corrective actions, 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 April 16, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 16, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2230; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material incorporated by reference in this AD, 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 at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–2230.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3228; email *Todd.Thompson@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 Deutsche Aircraft GmbH (Type Certificate previously held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and 328–300 airplanes. The NPRM published in the **Federal Register** on December 6, 2023 (88 FR 84764). The NPRM was prompted by AD 2023–0137, dated July 12, 2023 (EASA AD 2023–0137) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that operators reported findings of damaged affected parts. The extent of the detected damage of the affected parts did not ensure that appropriately low electrical impedance is obtained and maintained through the affected bonding path. The unsafe condition, if not detected and corrected, could lead to the loss of bonding function and, in combination with a lightning strike, create a source of ignition in a fuel tank, possibly resulting in a fire or explosion.

In the NPRM, the FAA proposed to require a one-time detailed inspection of each affected part, and applicable corrective actions, as specified in EASA AD 2023–0137. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2023–2230.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI 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 this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0137 specifies procedures for a one-time detailed inspection of each affected part for worn and ruptured bonding straps, and applicable corrective actions (replacing the affected parts). This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Interim Action

The FAA considers that this AD is an interim action. If final action is later identified, the FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this AD affects 35 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
44 work-hours × $85 per hour = $3,740	$0	$3,740	$130,900

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

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this AD.

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:

2024–03–07 Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH): Amendment 39–22677; Docket No. FAA–2023–2230; Project Identifier MCAI–2023–00861–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 16, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Deutsche Aircraft GmbH (Type Certificate previously held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and 328–300 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by operator reports of worn and ruptured bonding straps inside the feeder wing tanks and in both outer and inner wing tanks. The FAA is issuing this AD to address damaged bonding straps. The unsafe condition, if not addressed, could result in the loss of bonding function and, in combination with a lightning strike, create a source of ignition in a fuel tank, possibly resulting in a fire or explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0137, dated July 12, 2023 (EASA AD 2023–0137).

(h) Exceptions to EASA AD 2023–0137

(1) Where EASA AD 2023–0137 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0137.

(3) Where paragraph (2) of EASA AD 2023–0137 specifies if ''any damage is detected as defined in the ASB,'' this AD requires replacing those words with ''any worn or ruptured bonding strap is detected.''

(i) 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 (j) 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 Deutsche Aircraft GmbH's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Todd Thompson, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3228; email *Todd.Thompson@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0137, dated July 12, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0137, 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 EASA AD on the EASA website at *ad.easa.europa.eu.*

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

(5) You may view this 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 February 8, 2024.

Victor Wicklund,

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

[FR Doc. 2024–05192 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1810; Project Identifier MCAI–2023–00267–T; Amendment 39–22679; AD 2024–03–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A11 airplanes. This AD was prompted by a manufacturing issue with an electrical connector that may prevent the connector from self-locking. This AD requires removing the affected connector, installing a new connector, and testing the emergency power supply units (EPSUs), as specified in a Transport Canada 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 April 16, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 16, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1810; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1810.

FOR FURTHER INFORMATION CONTACT: William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Canada Limited Partnership Model BD–500–1A11 airplanes. The NPRM published in the **Federal Register** on August 31, 2023 (88 FR 60160). The NPRM was prompted by AD CF–2023–08, dated February 13, 2023, issued by Transport Canada, which is the aviation authority for Canada (Transport Canada AD CF–2023–08) (also referred to as the MCAI). The MCAI states that a manufacturing molding issue with an electrical connector may prevent the connector from self-locking. The connector may become loose over time, preventing the charging of EPSUs 3 and 4 and lead to the loss of emergency lights, possibly resulting in injury to occupants during an evacuation.

In the NPRM, the FAA proposed to require removing the affected connector, installing a new connector, and testing the EPSUs, as specified in Transport Canada AD CF–2023–08. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1810.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Delta Air Lines (DAL). The following presents the comment received on the NPRM and the FAA's response.

Request To Specify No U.S.-Registered Airplanes

DAL stated that via the FAA U.S. registry, the four affected airplanes are not U.S.-registered. The FAA assumes Delta would like the AD to specify no U.S.-registered airplanes.

The FAA agrees that the affected airplanes are not registered in the United States. The Costs of Compliance section of the final rule has been changed accordingly.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2023–08 specifies procedures for removing the affected connector, installing a new connector, and testing the EPSUs. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the

U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product
3.5 work-hours × $85 per hour = $298	$1,534	$1,832

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:

2024–03–09 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–22679; Docket No. FAA–2023–1810; Project Identifier MCAI–2023–00267–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 16, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–08, dated February 13, 2023 (Transport Canada AD CF–2023–08).

(d) Subject

Air Transport Association (ATA) of America Code: 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a manufacturing molding issue with an electrical connector that may prevent the connector from self-locking. The FAA is issuing this AD to ensure the connector does not become loose over time and prevent the charging of emergency power supply units (EPSUs) 3 and 4. The unsafe condition, if not addressed, could result in loss of emergency lights, possibly resulting in injury to occupants during an evacuation.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–08.

(h) Exception to Transport Canada AD CF–2023–08

Where Transport Canada AD CF–2023–08 refers to its effective date, this AD requires using the effective date of this AD.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the actions required by this AD can be accomplished, provided no passengers are onboard.

(j) 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 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.* 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 Transport Canada; or Airbus Canada Limited Partnership's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Additional Information

For more information about this AD, contact William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2023–08, dated February 13, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–08, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesde navigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*

(4) 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.

(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 March 5, 2024.

Victor Wicklund,

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

[FR Doc. 2024–05193 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 24–06]

RIN 1515–AE86

Extension of Import Restrictions Imposed on Archaeological and Ecclesiastical Ethnological Material From Honduras

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to extend import restrictions on certain archaeological and ecclesiastical ethnological material from Honduras. The Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has made the requisite determinations for extending the import restrictions, which were originally imposed by CBP Decision (CBP Dec.) 04–08 and last extended by CBP Dec. 19–03. The United States and Honduras have also agreed to extend the restrictions for an additional five-year period. Accordingly, these import restrictions will remain in effect for an additional five years, and the CBP regulations are being amended to reflect this further extension through March 12, 2029.

DATES: Effective March 12, 2024.

FOR FURTHER INFORMATION CONTACT: For legal aspects, W. Richmond Beevers, Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325–0084, *ot-otrrcultural property@cbp.dhs.gov.* For operational aspects, Julie L. Stoeber, Chief, 1USG Branch, Trade Policy and Programs, Office of Trade, (202) 945–7064, *1USGBranch@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Convention on Cultural Property Implementation Act (Pub. L. 97–446, 19 U.S.C. 2601 *et seq.*) (CPIA), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)) (the Convention), allows for the conclusion of an agreement between the United States and another party to the Convention to impose import restrictions on eligible archaeological and ethnological materials. Under the CPIA and the applicable U.S. Customs and Border Protection (CBP) regulations, found in §§ 12.104 through 12.104i of title 19 of the Code of Federal Regulations (19 CFR 12.104 through 12.104i), the restrictions are effective for no more than five years beginning on the date on which an agreement enters into force with respect to the United States (19 U.S.C. 2602(b)). This period may be extended for additional periods, each extension not to exceed five years, if it is determined that the factors justifying the initial agreement still pertain and no cause for suspension of the agreement exists (19 U.S.C. 2602(e); 19 CFR 12.104g(a)).

On March 12, 2004, the United States entered into a bilateral agreement with the Republic of Honduras (Honduras) to impose import restrictions on certain archaeological material representing the Pre-Columbian cultures of Honduras and ranging in date from approximately 1200 B.C. to 1500 A.D. On March 16, 2004, CBP published a final rule (CBP Dec. 04–08) in the **Federal Register** (69 FR 12267), which amended 19 CFR 12.104g(a) to reflect the imposition of these restrictions, and included a list designating the types of archaeological materials covered by the restrictions.

The import restrictions were subsequently extended three times in accordance with 19 U.S.C. 2602(e) and 19 CFR 12.104g(a), and the designated list was amended once. On March 11, 2009, CBP published a final rule (CBP Dec. 09–05) in the **Federal Register** (74 FR 10482), which amended § 12.104g(a) to reflect the extension of these import restrictions for an additional five years. On March 12, 2014, CBP published a final rule (CBP Dec. 14–03) in the **Federal Register** (79 FR 13873), which amended § 12.104g(a) to reflect the extension of these import restrictions for an additional five years as well as amending the Designated List to add restrictions on ecclesiastical ethological material dating to the Colonial period of Honduras, c. A.D. 1502 to 1821.

Subsequently, on March 5, 2019, the United States and Honduras entered into a superseding memorandum of understanding (MOU), that extended the import restrictions for an additional five years. On March 12, 2019, CBP published a final rule (CBP Dec. 19–03) in the **Federal Register** (84 FR 8807), which amended § 12.104g(a) to reflect the extension of these import restrictions for an additional five years. These import restrictions are due to expire on March 12, 2024.

On August 8, 2023, the United States Department of State proposed in the **Federal Register** (88 FR 53576) to extend the MOU. On January 24, 2024, after considering the views and recommendations of the Cultural Property Advisory Committee, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, made the necessary determinations to extend the import restrictions for an additional five years. Following an exchange of diplomatic notes, the United States Department of State and the Government of the Republic of Honduras have agreed to extend the restrictions for an additional five-year period, through March 12, 2029.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of these import restrictions. The restrictions on the importation of archaeological and ecclesiastical ethnological material from Honduras will continue in effect through March 12, 2029. Importation of such material from Honduras continues to be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

The Designated List and additional information may also be found at the following website address: *https://eca.state.gov/cultural-heritage-center/cultural-property/current-agreements-and-import-restrictions* by selecting the material for ''Honduras.''

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Executive Orders 12866 and 13563

Executive Orders 12866 (as amended by Executive Order 14094) 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 (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Orders 12866 and 13563 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866 and, by extension, Executive Order 13563.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of the Secretary's delegate) to approve regulations related to customs revenue functions.

Troy A. Miller, the Senior Official Performing the Duties of the Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to the Director (or Acting Director, if applicable) of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

Amendment to the CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, amend the table in paragraph (a) by revising the entry for Honduras to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
.		
* *	* * * * *	* *
Honduras	Archaeological material of Pre-Columbian cultures ranging approximately from 1200 B.C. to 1500 A.D, and ecclesiastical ethnological materials dating from the Colonial Period, c. A.D. 1502 to 1821.	CBP Dec. 14–03 extended by CBP Dec. 24–06.
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* *	* * * * *	* *

* * * * *

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury for Tax Policy.

[FR Doc. 2024–05345 Filed 3–8–24; 4:15 pm]

BILLING CODE 9111–14–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 583

Global Magnitsky Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending the Global Magnitsky Sanctions Regulations and reissuing them in their entirety to further implement the Global Magnitsky Human Rights Accountability Act and a December 20, 2017 Executive Order related to human rights and corruption. This final rule replaces the regulations that were published in abbreviated form on June 29, 2018, with a more comprehensive set of regulations that includes additional interpretive guidance and definitions, general licenses, and other regulatory provisions that will provide further guidance to the public. Due to the number of regulatory sections being updated or added, OFAC is reissuing the Global Magnitsky Sanctions Regulations in their entirety.

DATES: This rule is effective March 12, 2024.

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

SUPPLEMENTARY INFORMATION:

Electronic Availability

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

Background

On June 29, 2018, OFAC issued the Global Magnitsky Sanctions Regulations, 31 CFR part 583 (83 FR 30541, June 29, 2018) (the ''Regulations''), to implement the Global Magnitsky Human Rights Accountability Act (22 U.S.C. 10101–10103 (the ''Global Magnitsky Act'')) and Executive Order (E.O.) 13818 of December 20, 2017, ''Blocking the Property of Persons Involved in Serious Human Rights Abuse or Corruption'' (82 FR 60839, December 26, 2017), pursuant to authorities delegated to the Secretary of the Treasury. The Regulations were initially issued in abbreviated form for the purpose of providing immediate guidance to the public. OFAC is revising the Regulations to further implement the Global Magnitsky Act and E.O. 13818. OFAC is amending and reissuing the Regulations as a more comprehensive set of regulations that includes additional interpretive guidance and definitions, general licenses, and other regulatory provisions that will provide further guidance to the public. Finally, OFAC is adding the Uyghur Human Rights Policy Act of 2020, as amended, (22 U.S.C. 6901 note; Pub. L. 116–145, 134 Stat. 648) to the authority citation of 31 CFR part 583. Due to the number of regulatory sections being updated or added, OFAC is reissuing the Regulations in their entirety.

Global Magnitsky Act

On December 23, 2016, the President signed the Global Magnitsky Act into law. The Global Magnitsky Act, in section 1263 (22 U.S.C. 10102), authorizes the President to impose targeted sanctions on any foreign person the President determines, based on credible evidence: (1) is responsible for extrajudicial killings, torture, or other gross violations of internationally recognized human rights committed against individuals in any foreign country who seek (A) to expose illegal activity carried out by government officials; or (B) to obtain, exercise, defend, or promote internationally recognized human rights and freedoms, such as the freedoms of religion, expression, association, and assembly, and the rights to a fair trial and democratic elections; (2) acted as an agent of or on behalf of foreign persons in a matter related to an activity described in (1); (3) is a government official, or a senior associate of such an official, that is responsible for, or complicit in, ordering, controlling, or otherwise directing, acts of significant corruption including the expropriation of private or public assets for personal gain, corruption related to government contracts or the extraction of natural resources, bribery, or the facilitation or transfer of the proceeds of corruption to foreign jurisdictions; or (4) has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, an activity described in (3).

On September 8, 2017, the President delegated authority to the Secretary of the Treasury, in coordination with the Secretary of State, to administer the financial sanctions under section 1263 of the Global Magnitsky Act (22 U.S.C. 10102), which provides for the blocking of all property and interests in property of a foreign person described in section 1263(a) of the Global Magnitsky Act if such property and interests in property are in the United States, come within the United States, or are or come within the possession of or control of a United States person (82 FR 45411, September 28, 2017).

E.O. 13818

On December 20, 2017, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA) and the Global Magnitsky Act, issued E.O. 13818, effective at 12:01 a.m. eastern standard time on December 21, 2017, to implement and build upon the Global Magnitsky Act. In E.O. 13818, the President found that the prevalence and severity of human rights abuse and corruption that have their source, in whole or in substantial part, outside the United States, such as those committed or directed by persons listed in the Annex to E.O. 13818, have reached such scope and gravity that they threaten the stability of international political and economic systems. The President determined that serious human rights abuse and corruption around the world constitute an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States and declared a national emergency to deal with that threat.

Section 1(a) of E.O. 13818 blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of: (i) the persons listed in the Annex to E.O. 13818; (ii) any foreign person determined by the Secretary of the Treasury, in consultation with the Secretary of State and the Attorney General: (A) to be responsible for or complicit in, or to have directly or indirectly engaged in, serious human rights abuse; (B) to be a current or former government official, or a person acting for or on behalf of such an official, who is responsible for or complicit in, or has directly or indirectly engaged in: (1) corruption, including the misappropriation of state assets, the expropriation of private assets for personal gain, corruption related to government contracts or the extraction of natural resources, or bribery; or (2) the transfer or the facilitation of the transfer of the proceeds of corruption; (C) to be or have been a leader or official of: (1) an entity, including any government entity, that has engaged in, or whose members have engaged in, any of the activities described in subsection 1(ii)(A), (B)(1), or (B)(2) of E.O. 13818 relating to the leader's or official's tenure; or (2) an entity whose property and interests in property are blocked pursuant to this order as a result of activities related to the leader's or official's tenure; (D) to have attempted to engage in any of the activities described in subsection 1(ii)(A), (B)(1), or (B)(2) of E.O. 13818; and (iii) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State and the Attorney General: (A) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of: (1) any activity described in subsection 1(ii)(A), (B)(1), or (B)(2) of E.O. 13818 that is conducted by a foreign person; (2) any person whose property and interests in property are blocked pursuant to E.O. 13818; or (3) any entity, including any government entity, that has engaged in, or whose members have engaged in, any of the activities described in subsection 1(ii)(A), (B)(1), or (B)(2) of E.O. 13818, where the activity is conducted by a foreign person; (B) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this order; or (C) to have attempted to engage in any of the

activities described in subsection 1(iii)(A) or (B) of E.O. 13818. The property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, of the persons described above may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

Section 1(b) of E.O. 13818 provides that the prohibitions in Section 1(a) of E.O. 13818 apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to E.O. 13818, and notwithstanding any contract entered into or any license or permit granted before the effective date of E.O. 13818.

In Section 3 of E.O. 13818, the President determined that the making of donations of the types of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)), by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13818 would seriously impair the President's ability to deal with the national emergency declared in E.O. 13818. The President therefore prohibited the donation of such items except to the extent provided by statutes, or in regulations, rulings, instructions, orders, directives, or licenses that may be issued pursuant to E.O. 13818.

Section 4 of E.O. 13818 provides that the prohibition on any transaction or dealing in blocked property or interests in property includes the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13818, and the receipt of any contribution or provision of funds, goods, or services from any such person.

Section 5 of E.O. 13818 prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in E.O. 13818, as well as any conspiracy formed to violate such prohibitions.

Section 8 of E.O. 13818 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including adopting rules and regulations, and to employ all powers granted to the President by IEEPA and the Global Magnitsky Act, as may be necessary to implement E.O. 13818 and section 1263(a) of the Global Magnitsky Act (22 U.S.C. 10102(a)). Section 8 of E.O. 13818 also provides that the Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States.

Current Regulatory Action

To further implement the Global Magnitsky Act and E.O. 13818, OFAC is amending and reissuing the Regulations. The Regulations implement targeted sanctions that are directed at persons determined to meet the criteria set forth in § 583.201(a) of the Regulations, as well as sanctions that may be set forth in any further Executive orders issued pursuant to the national emergency declared in E.O. 13818. The sanctions in E.O. 13818 do not generally prohibit trade or the provision of banking or other financial services to a certain country. Instead, the sanctions in E.O. 13818 apply where the transaction or service in question involves property or interests in property that are blocked pursuant to these authorities.

Subpart A of the Regulations clarifies the relation of this part to other laws and regulations. Subpart B of the Regulations implements the prohibitions contained in sections 1, 3, 4, and 5 of E.O. 13818, which implement and build upon the prohibitions set forth in the Global Magnitsky Act, the prohibitions contained in any further Executive orders issued pursuant to the national emergency declared in E.O. 13818. Persons identified in the Annex to E.O. 13818, designated by or under the authority of the Secretary of the Treasury pursuant to E.O. 13818, or otherwise blocked pursuant to E.O. 13818, as well as persons who are blocked pursuant to any further Executive orders issued pursuant to the national emergency declared in E.O. 13818, are referred to throughout the Regulations as ''persons whose property and interests in property are blocked pursuant to § 583.201.'' The names of persons designated or identified as blocked pursuant to E.O. 13818, or any further Executive orders issued pursuant to the national emergency declared therein, are published on OFAC's SDN List, which is accessible via OFAC's website. Those names also are published in the **Federal Register** as they are added to the SDN List.

Sections 583.202 and 583.203 of subpart B detail the effect of transfers of blocked property in violation of the Regulations and set forth the requirement to hold blocked funds, such as currency, bank deposits, or liquidated financial obligations, in interest-bearing blocked accounts. Section 583.204 of subpart B provides that all expenses incident to the maintenance of blocked tangible property shall be the responsibility of the owners and operators of such property, and that such expenses shall not be met from blocked funds, unless otherwise authorized. The section further provides that blocked property may, in OFAC's discretion, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

Section 583.205 of subpart B prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in section 583.201 of the Regulations, and any conspiracy formed to violate such prohibitions.

Section 583.206 of subpart B details transactions that are exempt from the prohibitions of the Regulations pursuant to section 203(b) of IEEPA (50 U.S.C. 1702(b)).

In subpart D, which contains interpretive sections regarding the Regulations, certain provisions have been renumbered and others added to those in the prior abbreviated set of regulations. Section 583.411 of subpart D explains that the property and interests in property of an entity are blocked if the entity is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked, whether or not the entity itself is incorporated into OFAC's SDN List.

Transactions otherwise prohibited by the Regulations but found to be consistent with U.S. policy may be authorized by one of the general licenses contained in or issued pursuant to subpart E of the Regulations or by a specific license issued pursuant to the procedures described in subpart E of 31 CFR part 501. General licenses and statements of licensing policy relating to this part also may be available through the Global Magnitsky sanctions page on OFAC's website: *www.treas.gov/ofac.*

Subpart F of the Regulations refers to subpart C of part 501 for recordkeeping and reporting requirements. Subpart G of the Regulations describes the civil and criminal penalties applicable to violations of the Regulations, as well as the procedures governing the potential imposition of a civil monetary penalty or issuance of a Finding of Violation. Subpart G also refers to appendix A of part 501 for a more complete description of these procedures.

Subpart H of the Regulations refers to subpart E of part 501 for applicable provisions relating to administrative procedures and contains a delegation of certain authorities of the Secretary of the Treasury. Subpart I of the

Regulations sets forth a Paperwork Reduction Act notice.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. 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.

List of Subjects in 31 CFR Part 583

Administrative practice and procedure, Banks, Banking, Blocking of assets, Corruption, Credit, Foreign trade, Global Magnitsky, Human rights, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services.

For the reasons set forth in the preamble, OFAC revises 31 CFR part 583 to read as follows:

PART 583—GLOBAL MAGNITSKY SANCTIONS REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Sec.

583.101 Relation of this part to other laws and regulations.
583.102 Records and Reports.
583.103 Procedures.
583.104 Paperwork Reduction Act notice.
583.105 [Reserved]
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Subpart A—Relation of This Part to Other Laws and Regulations

§ 583.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

§ 583.102 Records and reports.

For provisions relating to required records and reports, see part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

§ 583.103 Procedures.

For license application procedures and procedures relating to amendments, modifications, or revocations of licenses; administrative decisions; rulemaking; and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), see part 501, subpart E, of this chapter.

§ 583.104 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures, and other procedures, see § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

§ 583.105 [Reserved]

§ 583.106 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to E.O. 13818, any further Executive orders relating to the national emergency declared therein, or Presidential Memorandum of December 7, 2023: Delegation of Certain Functions and Authorities Under the Uyghur Human Rights Policy Act of 2020 and Public Law 117–78, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority to so act.

Subpart B—Prohibitions

§ 583.201 Prohibited transactions.

(a) All property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(1) *Executive Order (E.O.) 13818 Annex.* The persons listed in the Annex to E.O. 13818 of December 20, 2017.

(2) *E.O. 13818.* Any foreign person determined by the Secretary of the Treasury, in consultation with the Secretary of State and the Attorney General:

(i) To be responsible for or complicit in, or to have directly or indirectly engaged in, serious human rights abuse;

(ii) To be a current or former government official, or a person acting for or on behalf of such an official, who is responsible for or complicit in, or has directly or indirectly engaged in:

(A) Corruption, including the misappropriation of state assets, the expropriation of private assets for personal gain, corruption related to government contracts or the extraction of natural resources, or bribery; or

(B) The transfer or the facilitation of the transfer of the proceeds of corruption;

(iii) To be or have been a leader or official of:

(A) An entity, including any government entity, that has engaged in, or whose members have engaged in, any of the activities described in paragraph (a)(2)(i), (a)(2)(ii)(A), or (a)(2)(ii)(B) of this section relating to the leader's or official's tenure; or

(B) An entity whose property and interests in property are blocked pursuant to this order as a result of activities related to the leader's or official's tenure;

(iv) To have attempted to engage in any of the activities described in paragraph (a)(2)(i), (a)(2)(ii)(A), or (a)(2)(ii)(B) of this section; and

(v) To have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of:

(A) Any activity described in paragraph (a)(2)(i), (a)(2)(ii)(A), or (a)(2)(ii)(B) of this section that is conducted by a foreign person;

(B) Any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; or

(C) Any entity, including any government entity, that has engaged in, or whose members have engaged in, any of the activities described in paragraph (a)(2)(i), (a)(2)(ii)(A), or (a)(2)(ii)(B) of this section, where the activity is conducted by a foreign person;

(vi) To be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; or

(vii) To have attempted to engage in any of the activities described in paragraph (a)(2)(v) or (a)(2)(vi) of this section.

(b) The prohibitions in paragraph (a) of this section include prohibitions on the following transactions:

(1) The making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; and

(2) The receipt of any contribution or provision of funds, goods, or services from any person whose property and interests in property are blocked pursuant to paragraph (a) of this section.

(c) Unless authorized by this part or by a specific license expressly referring to this part, any dealing in securities (or evidence thereof) held within the possession or control of a U.S. person and either registered or inscribed in the name of, or known to be held for the benefit of, or issued by, any person whose property and interests in property are blocked pursuant to paragraph (a) of this section is prohibited. This prohibition includes the transfer (including the transfer on the books of any issuer or agent thereof), disposition, transportation, importation, exportation, or withdrawal of, or the endorsement or guaranty of signatures on, any securities on or after the effective date. This prohibition applies irrespective of the fact that at any time (whether prior to, on, or subsequent to the effective date) the registered or inscribed owner of any such securities may have or might appear to have assigned, transferred, or otherwise disposed of the securities.

(d) The prohibitions in paragraph (a) of this section apply except to the extent provided by statutes, or in regulations, rulings, instructions, orders, directives, or licenses that may be issued pursuant to this part, and notwithstanding any contract entered into or any license or permit granted prior to the effective date.

(e) All transactions prohibited pursuant to any Executive order issued after December 20, 2017 pursuant to the national emergency declared in E.O. 13818 of December 20, 2017 are prohibited pursuant to this part.

Note 1 to § 583.201. The names of persons designated or identified as blocked pursuant to E.O. 13818, or any further Executive orders issued pursuant to the national emergency declared therein, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) using the following identifiers: for E.O. 13818: ''[GLOMAG]''; and for any further Executive orders issued pursuant to the national emergency declared in E.O. 13818: using the identifier formulation ''[GLOMAG–E.O. [E.O. number pursuant to which the person's property and interests in property are blocked]]''. The SDN List is accessible through the following page on OFAC's website: *www.treas.gov/sdn.* Additional information pertaining to the SDN List can be found in appendix A to this chapter. *See* § 583.411 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 583.201. The International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), in section 203 (50 U.S.C. 1702) authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the **Federal Register** and incorporated into the SDN List using the following identifiers: for E.O. 13818: ''[BPI–GLOMAG]''; for any further Executive orders issued pursuant to the national emergency declared in E.O. 13818: using the identifier formulation ''[BPI–GLOMAG–E.O. [E.O. number pursuant to which the person's property and interests in property are blocked pending investigation]].''

Note 3 to § 583.201. Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

§ 583.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, ruling, instruction, order, directive, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 583.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or interest in property.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 583.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for the provisions of this part and any regulation, ruling, instruction, order, directive, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, order, directive, license, or other authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

(e) The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(f) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property or interest in property blocked pursuant to § 583.201.

§ 583.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 583.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For the purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For the purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For the purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 583.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 583.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as real or personal property, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, OFAC may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds blocked pursuant to § 583.201 may not be held, invested, or reinvested in a manner that provides financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 583.201, nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 583.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of tangible property blocked pursuant to § 583.201 shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 583.201 may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

§ 583.205 Evasions; attempts; causing violations; conspiracies.

(a) Any transaction on or after the effective date that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Any conspiracy formed to violate the prohibitions set forth in this part is prohibited.

§ 583.206 Exempt transactions.

The prohibitions contained in this part do not apply to any transactions that are exempt pursuant to section 203(b) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)).

Subpart C—General Definitions

§ 583.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 583.301 Blocked account; blocked property.

The terms *blocked account* and *blocked property* mean any account or property subject to the prohibitions in § 583.201 held in the name of a person whose property and interests in property are blocked pursuant to § 583.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note 1 to § 583.301. *See* § 583.411 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 583.201.

§ 583.302 Effective date.

(a) The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(1) With respect to a person whose property and interests in property are blocked pursuant to § 583.201(a)(1), 12:01 a.m. eastern standard time on December 21, 2017; and

(2) With respect to a person whose property and interests in property are otherwise blocked pursuant to § 583.201, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

(b) For the purposes of this section, *constructive notice* is the date that a notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

§ 583.303 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

§ 583.304 Financial, material, or technological support.

The term *financial, material, or technological support* means any property, tangible or intangible, including currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods. ''Technologies'' as used in this section means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

§ 583.305 Foreign person.

The term *foreign person* means any citizen or national of a foreign state (including any such individual who is also a citizen or national of the United States), or any entity not organized solely under the laws of the United States or existing solely in the United States, but does not include a foreign state.

§ 583.306 [Reserved]

§ 583.307 Interest.

Except as otherwise provided in this part, the term *interest,* when used with respect to property (*e.g.,* ''an interest in property''), means an interest of any nature whatsoever, direct or indirect.

§ 583.308 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC's website: *https://ofac.treasury.gov.*

(c) The term *specific license* means any license or authorization issued pursuant to this part but not set forth in subpart E of this part or made available on OFAC's website: *https://ofac.treasury.gov.*

Note 1 to § 583.308. *See* § 501.801 of this chapter on licensing procedures.

§ 583.309 OFAC.

The term *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

§ 583.310 Person.

The term *person* means an individual or entity.

§ 583.311 Property; property interest.

The terms *property* and *property interest* include money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership, or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest

or interests therein, present, future, or contingent.

§ 583.312 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, filing, or levy of or under any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 583.313 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 583.314 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, lawful permanent resident, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

§ 583.315 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, purchasing or selling foreign exchange, securities, futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, money services businesses, operators of credit card systems, trust companies, insurance companies, securities brokers and dealers, futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

Subpart D—Interpretations

§ 583.401 Reference to amended sections.

(a) Reference to any section in this part is a reference to the same as currently amended, unless the reference includes a specific date. *See* 44 U.S.C. 1510.

(b) Reference to any regulation, ruling, instruction, order, directive, or license issued pursuant to this part is a reference to the same as currently amended unless otherwise so specified.

§ 583.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any regulation, ruling, insruction, order, directive, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such regulation, ruling, instruction, order, directive, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 583.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 583.201, such property shall no longer be deemed to be property blocked pursuant to § 583.201, unless there exists in the property another interest that is blocked pursuant to § 583.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 583.201, such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 583.404 Transactions ordinarily incident to a licensed transaction.

(a) Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(1) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 583.201; or

(2) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

(b) For example, a license authorizing a person to complete a securities sale involving Company A, whose property and interests in property are blocked pursuant to § 583.201, also authorizes other persons to engage in activities that are ordinarily incident and necessary to complete the sale, including transactions by the buyer, broker, transfer agents, and banks, provided that such other persons are not themselves persons whose property and interests in property are blocked pursuant to § 583.201.

§ 583.405 Provision and receipt of services.

(a) The prohibitions contained in § 583.201 apply to services performed in the United States or by U.S. persons, wherever located:

(1) On behalf of or for the benefit of any person whose property and interests in property are blocked pursuant to § 583.201; or

(2) With respect to property interests of any person whose property and interests in property are blocked pursuant to § 583.201.

(b) The prohibitions on transactions contained in § 583.201 apply to services received in the United States or by U.S. persons, wherever located, where the service is performed by, or at the direction of, a person whose property and interests in property are blocked pursuant to § 583.201.

(c) For example, U.S. persons may not, except as authorized by or pursuant to this part, provide legal, accounting,

financial, brokering, freight forwarding, transportation, public relations, or other services to any person whose property and interests in property are blocked pursuant to § 583.201, or negotiate with or enter into contracts signed by a person whose property and interests in property are blocked pursuant to § 583.201.

Note 1 to § 583.405. *See* §§ 583.507 and 583.509 for general licenses authorizing the provision of certain legal and emergency medical services.

§ 583.406 Offshore transactions involving blocked property.

The prohibitions in § 583.201 on transactions or dealings involving blocked property, as defined in § 583.301, apply to transactions by any U.S. person in a location outside the United States.

§ 583.407 Payments from blocked accounts to satisfy obligations prohibited.

Pursuant to § 583.201, no debits may be made to a blocked account to pay obligations to U.S. persons or other persons, except as authorized by or pursuant to this part.

Note 1 to § 583.407. *See also* § 583.502(e), which provides that no license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

§ 583.408 Charitable contributions.

Unless specifically authorized by OFAC pursuant to this part, no charitable contribution of funds, goods, services, or technology, including contributions to relieve human suffering, such as food, clothing, or medicine, may be made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 583.201. For the purposes of this part, a contribution is made by, to, or for the benefit of, or received from a person whose property and interests in property are blocked pursuant to § 583.201 if made by, to, or in the name of, or received from or in the name of, such a person; if made by, to, or in the name of, or received from or in the name of, an entity or individual acting for or on behalf of, or owned or controlled by, such a person; or if made in an attempt to violate, to evade, or to avoid the bar on the provision of contributions by, to, or for the benefit of such a person, or the receipt of contributions from such a person.

§ 583.409 Credit extended and cards issued by financial institutions to a person whose property and interests in property are blocked.

The prohibition in § 583.201 on dealing in property subject to that section prohibits U.S. financial institutions from performing under any existing credit agreements, including charge cards, debit cards, or other credit facilities issued by a financial institution to a person whose property and interests in property are blocked pursuant to § 583.201.

§ 583.410 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. financial institution or other U.S. person, is a prohibited transfer under § 583.201 if effected after the effective date.

§ 583.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 583.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 583.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

§ 583.412 Entities of which one or more blocked persons is a member, leader, official, senior executive officer, or otherwise exercises control.

(a) The property and interests in property of an entity, including any political subdivision, agency, or instrumentality of a governmental entity, are not blocked solely because one or more persons whose property and interests in property are blocked pursuant to § 583.201 is a member, leader, official, senior executive officer, or otherwise exercises control.

Note 1 to paragraph (a). *See* § 583.411 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 583.201.

(b) For example, U.S. persons may not, except as authorized or exempt pursuant to this part, engage in the following transactions with a person whose property and interests in property are blocked pursuant to § 583.201: enter into contracts that are signed by a blocked person, enter into negotiations with a blocked person, or process transactions, directly or indirectly, on behalf of a person whose property and interests in property are blocked pursuant to § 583.201. However, U.S. persons are not prohibited from engaging in a routine interaction with an agency in which a blocked person is an official, but which does not involve the blocked person directly or indirectly.

Note 2 to § 583.412. OFAC encourages U.S. persons to be cautious in engaging in transactions with any entity of which a person whose property and interests in property are blocked pursuant to § 583.201 is a member, leader, official, senior executive officer, or otherwise exercises control to ensure that U.S. persons are not engaged in transactions, directly or indirectly, with a blocked person, except as authorized or exempt pursuant to this part.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 583.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Global Magnitsky sanctions page on OFAC's website: *www.treas.gov/ofac.*

§ 583.502 Effect of license or other authorization.

(a) No license or other authorization contained in this part, or otherwise issued by OFAC, authorizes or validates any transaction effected prior to the issuance of such license or other authorization, unless specifically provided in such license or authorization.

(b) No regulation, ruling, instruction, order, directive, or license authorizes any transaction prohibited under this part unless the regulation, ruling, instruction, order, directive, or license is issued by OFAC and specifically refers to this part. No regulation, ruling, instruction, order, directive, or license referring to this part shall be deemed to authorize any transaction prohibited by any other part of this chapter unless the regulation, ruling, instruction, order, directive, or license specifically refers to such part.

(c) Any regulation, ruling, instruction, order, directive, or license authorizing any transaction prohibited under this part has the effect of removing a prohibition contained in this part from the transaction, but only to the extent

specifically stated by its terms. Unless the regulation, ruling, instruction, order, directive, or license otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(d) Nothing contained in this part shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain a license or other authorization from another department or agency of the U.S. government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency. For example, exports of goods, services, or technical data that are not prohibited by this part or that do not require a license by OFAC nevertheless may require authorization by the U.S. Department of Commerce, the U.S. Department of State, or other agencies of the U.S. government.

(e) No license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

(f) Any payment relating to a transaction authorized in or pursuant to this part that is routed through the U.S. financial system should reference the relevant OFAC general or specific license authorizing the payment to avoid the blocking or rejection of the transfer.

§ 583.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 583.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 583.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note 1 to § 583.504. *See* § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 583.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 583.505 Entries in certain accounts for normal service charges.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charges* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 583.506 Investment and reinvestment of certain funds.

Subject to the requirements of § 583.203, U.S. financial institutions are authorized to invest and reinvest assets blocked pursuant to § 583.201, subject to the following conditions:

(a) The assets representing such investments and reinvestments are credited to a blocked account or subaccount that is held in the same name at the same U.S. financial institution, or within the possession or control of a U.S. person, but funds shall not be transferred outside the United States for this purpose;

(b) The proceeds of such investments and reinvestments shall not be credited to a blocked account or subaccount under any name or designation that differs from the name or designation of the specific blocked account or subaccount in which such funds or securities were held; and

(c) No immediate financial or economic benefit accrues (*e.g.,* through pledging or other use) to a person whose property and interests in property are blocked pursuant to § 583.201.

§ 583.507 Provision of certain legal services.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 583.201, is authorized, provided that any receipt of payment of professional fees and reimbursement of incurred expenses must be authorized pursuant to § 583.508, which authorizes certain payments for legal services from funds originating outside the United States; via specific license; or otherwise pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 583.201, not otherwise authorized in this part, requires the issuance of a specific license.

(c) U.S. persons do not need to obtain specific authorization to provide related services, such as making filings and providing other administrative services, that are ordinarily incident to the provision of services authorized by paragraph (a) of this section. Additionally, U.S. persons who provide services authorized by paragraph (a) of this section do not need to obtain specific authorization to contract for related services that are ordinarily incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. *See* § 583.404.

(d) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or

other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 583.201 is prohibited unless licensed pursuant to this part.

Note 1 to § 583.507. Pursuant to part 501, subpart E, of this chapter, U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of certain blocked funds for the payment of professional fees and reimbursement of incurred expenses for the provision of such legal services where alternative funding sources are not available.

§ 583.508 Payments for legal services from funds originating outside the United States.

(a) *Professional fees and incurred expenses.* (1) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 583.507(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 583.201 is authorized from funds originating outside the United States, provided that the funds do not originate from:

(i) A source within the United States;

(ii) Any source, wherever located, within the possession or control of a U.S. person; or

(iii) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 583.507(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order or statute.

(2) Nothing in this paragraph (a) authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 583.201, any other part of this chapter, or any Executive order or statute has an interest.

(b) *Records.* Consistent with § 501.601 of this chapter, U.S. persons who receive payments pursuant to paragraph (a) of this section must retain for five years from the date of the relevant payment a record that specifies the following for each payment:

(1) The individual or entity from whom the funds originated and the amount of funds received; and

(2) If applicable:

(i) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(ii) A general description of the services provided; and

(iii) The amount of funds paid in connection with such services.

(3) These records must be furnished to OFAC on demand consistent with § 501.602 of this chapter.

§ 583.509 Emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are prohibited by this part are authorized.

§ 583.510 Official business of the United States government.

All transactions prohibited by this part that are for the conduct of the official business of the United States government by employees, grantees, or contractors thereof are authorized.

§ 583.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

§ 583.512 Certain transactions in support of nongovernmental organizations' activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 583.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

§ 583.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 583.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

Subpart F—[Reserved]

Subpart G—Penalties and Findings of Violation

§ 583.701 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) (IEEPA) is applicable to violations of the provisions of any regulation in this part, ruling, instruction, order, directive, or license issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any regulation, ruling, instruction, order, directive, license, or prohibition issued under IEEPA.

(2) IEEPA provides for a maximum civil penalty not to exceed the greater of $368,136 or an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(3) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any regulation in this part, ruling, instruction, order, directive, license, or prohibition may, upon conviction, be fined not more than $1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b)(1) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(2) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(c) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(d) Violations of this part may also be subject to other applicable laws.

§ 583.702 Pre-Penalty Notice; settlement.

(a) *When required.* If OFAC has reason to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any regulation, ruling, instruction, order, directive, or license issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and determines that a civil monetary penalty is warranted, OFAC will issue a Pre-Penalty Notice informing the alleged violator of the agency's intent to impose a monetary penalty. A Pre-Penalty Notice shall be in writing. The Pre-Penalty Notice may be issued whether or not another agency has taken any action with respect to the matter. For a description of the contents of a Pre-Penalty Notice, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to respond to a Pre-Penalty Notice by making a written presentation to OFAC. For a description of the information that should be included in such a response, see appendix A to part 501 of this chapter.

(2) *Deadline for response.* A response to a Pre-Penalty Notice must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a Pre-Penalty Notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the Pre-Penalty Notice was mailed or date the Pre-Penalty Notice was emailed. If the Pre-Penalty Notice was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a Federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to a Pre-Penalty Notice need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the Pre-Penalty Notice, and include the OFAC identification number listed on the Pre-Penalty Notice. The response must be sent to OFAC's Enforcement Division by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(c) *Settlement.* Settlement discussion may be initiated by OFAC, the alleged

violator, or the alleged violator's authorized representative. For a description of practices with respect to settlement, see appendix A to part 501 of this chapter.

(d) *Guidelines.* Guidelines for the imposition or settlement of civil penalties by OFAC are contained in appendix A to part 501 of this chapter.

(e) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific allegations contained in the Pre-Penalty Notice must be preceded by a written letter of representation, unless the Pre-Penalty Notice was served upon the alleged violator in care of the representative.

§ 583.703 Penalty imposition.

If, after considering any written response to the Pre-Penalty Notice and any relevant facts, OFAC determines that there was a violation by the alleged violator named in the Pre-Penalty Notice and that a civil monetary penalty is appropriate, OFAC may issue a Penalty Notice to the violator containing a determination of the violation and the imposition of the monetary penalty. For additional details concerning issuance of a Penalty Notice, see appendix A to part 501 of this chapter. The issuance of the Penalty Notice shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in Federal district court.

§ 583.704 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to OFAC, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a Federal district court.

§ 583.705 Findings of Violation.

(a) *When issued.* (1) OFAC may issue an initial Finding of Violation that identifies a violation if OFAC:

(i) Determines that there has occurred a violation of any provision of this part, or a violation of the provisions of any regulation, ruling, instruction, order, directive, or license issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*);

(ii) Considers it important to document the occurrence of a violation; and

(iii) Based on the Guidelines contained in appendix A to part 501 of this chapter, concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial Finding of Violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter. For additional details concerning issuance of a Finding of Violation, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to contest an initial Finding of Violation by providing a written response to OFAC.

(2) *Deadline for response; default determination.* A response to an initial Finding of Violation must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial Finding of Violation will become final and will constitute final agency action. The violator has the right to seek judicial review of that final agency action in Federal district court.

(i) *Computation of time for response.* A response to an initial Finding of Violation must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the initial Finding of Violation was served or date the Finding of Violation was sent by email. If the initial Finding of Violation was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to an initial Finding of Violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the initial Finding of Violation, and include the OFAC identification number listed on the initial Finding of Violation. The response must be sent to OFAC's Enforcement Division by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the regulations in this part did not occur and/or why a Finding of Violation is otherwise unwarranted under the circumstances, with reference to the General Factors Affecting Administrative Action set forth in the Guidelines contained in appendix A to part 501 of this chapter. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted in the response.

(c) *Determination*—(1) *Determination that a Finding of Violation is warranted.* If, after considering the response, OFAC determines that a final Finding of Violation should be issued, OFAC will issue a final Finding of Violation that will inform the violator of its decision. A final Finding of Violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in Federal district court.

(2) *Determination that a Finding of Violation is not warranted.* If, after considering the response, OFAC determines a Finding of Violation is not warranted, then OFAC will inform the alleged violator of its decision not to issue a final Finding of Violation.

Note 1 to paragraph (c)(2). A determination by OFAC that a final Finding of Violation is not warranted does not preclude OFAC from pursuing other enforcement actions consistent with the Guidelines contained in appendix A to part 501 of this chapter.

(d) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific alleged violations contained in the initial Finding of Violation must be preceded by a written letter of representation, unless the initial Finding of Violation was served upon the alleged violator in care of the representative.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–05207 Filed 3–11–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 236

[Docket ID: DoD–2019–OS–0112]

RIN 0790–AK86

Department of Defense (DoD) Defense Industrial Base (DIB) Cybersecurity (CS) Activities

AGENCY: Office of the DoD Chief Information Officer, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The DoD is finalizing revisions to the eligibility criteria for the voluntary Defense Industrial Base (DIB) Cybersecurity (CS) Program. These revisions will allow all defense contractors who own or operate an unclassified information system that processes, stores, or transmits covered defense information to benefit from bilateral information sharing. DoD is also finalizing changes to definitions and some technical corrections for readability.

DATES: This rule is effective on April 11, 2024.

FOR FURTHER INFORMATION CONTACT:

- Stacy Bostjanick, Chief Defense Industrial Base Cybersecurity, Office: 703–604–3167.
- DIB CS Program Management Office: *OSD.DIBCSIA@mail.mil.*

SUPPLEMENTARY INFORMATION:

Discussion of Comments and Changes

The proposed rule was published in the **Federal Register** (88 FR 27832–27839) on May 3, 2023. Four submissions were received and are summarized below.

A commenter suggested DoD should redefine terms and should change the regulations for the program. However, the commenter did not provide any additional detail which would allow DoD to consider possible changes.

A commenter suggested DoD use this opportunity to run a targeted marketing campaign to assist small businesses with explaining a medium assurance certificate's purpose and procuring the hardware in advance of needing it.

After consideration, DoD is modifying the requirement for industry to obtain a medium assurance certificate. Medium assurance certificates can be used to validate digital identity and facilitate the exchange of encrypted information. However, it is not the only technical solution available to support identity proofing requirements. So, DoD is revising paragraph (e) in § 236.4, and separately in Department of Defense Instruction (DoDI) 8582.01, ''Security of Non-DoD Information Systems Processing Unclassified Nonpublic DoD Information,'' to require registration with Procurement Integrated Enterprise Environment (PIEE) [1] when submitting mandatory cyber incident reports. This change will reduce the burden of having to procure a medium assurance certificate which costs approximately $175 annually. All DoD contracts contain Defense Federal Acquisition Regulation Supplement (DFARS) clause 252.232–7003 (48 CFR 252.232–7003), which specifies requirements for electronic submission of payment requests. In order to access the electronic systems associated with electronic payments the contractor must also complete the required identity proofing and registration process with PIEE.

Multiple commenters provided input on the accuracy of the burden estimates. One commentor recommended allowing one report to cover multiple contracts to reduce the administrative reporting burden on all parties and enhance consistency across DoD data. Another commentor noted that many firms will lack in-depth familiarity with existing policy, compliance requirements, and other details of the DIB CS Program and, as such, the estimate of 30 minutes for new entrants to familiarize themselves with the rule is an underestimate.

As DoD is modifying the requirement for industry to obtain a medium assurance certificate with this final rule, the Department believes the burden to companies participating in the DIB CS Program is being reduced. In response to concerns about submitting a nearly identical report for multiple contracts, DoD would like to clarify that a contractor may submit one report for an event that impacts multiple contracts. Finally, DoD would like to clarify the estimate of 30 minutes to review changes to this final rule and choose whether to apply to the voluntary DIB CS Program does not include time for contractors to develop in-depth familiarity with existing policies and compliance requirements. It is expected DoD contractors will invest time to familiarize themselves with contractually mandated requirements in addition to this estimate.

A commenter highlighted the revision to the DIB CS Program omits a key component of the Critical Infrastructure Protection Act (CIPA) of 2001, and the revisions to the DIB CS Program will exclude operationally critical support (OCS) contractors from its provisions unless such contractors have covered defense information (CDI) resident in their information systems (IS). The commenter recommended including contractors performing under contracts that are designated as providing OCS, regardless of whether those IS contain CDI.

In accordance with 10 U.S.C. 391, the DoD must include mechanisms for Department personnel to, if requested, assist operationally critical contractors in detecting and mitigating penetrations. Pursuant to section 1642(b) of the National Defense Authorization Act for Fiscal Year 2019 DoD has authority to engage with the DIB that is complementary to, but distinct from, the DIB Cybersecurity Activities that implement the requirements levied upon the Department in 10 U.S.C. 391 and 393. To meet the requirements specified in 10 U.S.C. 391, the DIB CS program will refer ineligible applicants to other U.S. Government Departments and Agencies sharing cybersecurity equities to ensure Federal unity of effort.

A commenter posed several questions about the role of third-party service providers seeking to understand if a third-party service provider may submit reports on behalf of a client, and if a third-party service provider must own or operate covered contractor information systems.

Currently, a contractor may authorize a third-party service provider to report incidents on behalf of the contractor. If that contractor and the third-party service provider are interested in participating in the DIB CS Program, an amendment to the DIB CS Program Framework Agreement is available to authorize the third-party service provider access to DIB CS resources. This agreement details whether the third-party service provider will provide on-site or off-site support; clarifies the respective roles of the contractor and the third-party service provider regarding accessing the government-furnished information on the DIB CS web portal and voluntary reporting of cyber incidents and indicators to the Government. The Framework Agreement and all Program amendments are made available through *https://dibnet.dod.mil* to an eligible company after the company has been verified by the DoD. The third-party service provider does not need to own or operate a covered defense system.

Two commenters reiterated the need for training and best practices but did not indicate if they are familiar with DoD's current training programs or if they believe the programs are adequate.

[1] *https://piee.eb.mil/.*

DoD notes the DIB CS Program offers training and best practices through in-person and virtual meetings and provides information about digital resources on *https://dibnet.dod.mil.*

One commenter stated a link or a copy of the ''standardized'' Government Framework Agreement on the website will help contractors better understand their ability to meet the requirement before submitting an application—potentially saving all parties time and resources.

DoD notes factsheets and informational materials are publicly available on *https://dibnet.dod.mil.* The Framework Agreement between the Government and a DIB participant is made available after the company applies to the program and DoD verifies the company meets the eligibility requirements set forth in § 236.7.

A commenter suggested access and information for cleared companies should remain as it is today and recommended an ''impact statement'' to information released to uncleared firms to help contextualize the information and the reason for disseminating it.

The Privacy Impact Assessment (PIA) for DoD's DIB CS Activities provides procedures on how the Government handles personally identifiable information (PII), as well as other forms of sensitive contractor information (*e.g.,* contractor attributional/proprietary). The PIA is publicly available at *https://dodcio.defense.gov/Portals/0/Documents/DIB_PIA.pdf and no changes to the PIA are being proposed.* The Security Classification Guide (SCG) [2] is the tool used by DoD Personnel to identify and safeguard national security information when derivatively classifying information. All information will be designated and handled in accordance with the DIB CS Activities SCG, the NISPOM Program as defined in 32 CFR part 117 and the Controlled Unclassified Information (CUI) Program as defined in 32 CFR part 2002.

A commenter asked about a future opportunity to map the level of access to DIB CS resources to a company's certification(s) level or assessment scoring.

DoD notes all companies currently participating in the DIB CS Program are eligible to receive Government Furnished Information (GFI) under the voluntary DIB CS Program and cybersecurity information is shared to the greatest extent possible in accordance with the Program's SCG. Information about a company's certification level or assessment score is controlled information and not available to the DIB CS Program at this time.

A commenter recommended providing consistent controls and data access channels to help companies synthesize and apply the threat information to their market.

The DIB CS Program marks all documents in accordance with the SCG [3] and DIBNet remains the primary channel for disseminating threat products. DoD has recently relaunched DIBNet to provide an API-based data access channel to complement the ability for a DIB CS Participant to download PDF, TXT, and CSV based products which should allow a participating company to analyze threat information unique to their market.

A commenter recommended adding headers to § 236.4 for paragraph (f), (g), (j), and (o) to increase uniformity.

DoD has added headers to § 236.4 for paragraphs (f), (g), and (o). Paragraph (j) has a header, and an administrative correction will be made to correct the format of paragraph (n).

A commenter asked if the rights and responsibilities for submittals under the DIB CS Program have changed with respect to Freedom of Information Act (FOIA).

The rights and responsibilities for submittals under the DIB CS Program have not changed with respect to Freedom of Information Act (FOIA). The Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency (OATSD(PCLT)) maintains a DoD FOIA Handbook available at *https://open.defense.gov/Transparency/FOIA/FOIA Handbook.aspx.*

Background and Authority

The DIB means the DoD, Government, and private sector worldwide industrial complex with capabilities to perform research and development, design, produce, and maintain military weapon systems, subsystems, components, or parts to satisfy military requirements. The DIB Cybersecurity Program is a voluntary program to enhance and supplement participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems. The program encourages greater threat information sharing to complement mandatory aspects of DoD's DIB cybersecurity activities which are contractually mandated through DFARS 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting.[4] This program supports and complements DoD-specific authorities at 10 U.S.C. 2224 and the Federal Information Security Management Act (FISMA 2002) as amended by the Federal Information Security Modernization Act, 2014. Cyber threat information sharing activities under this final rule also fulfill important elements of DoD's critical infrastructure protection responsibilities, as the sector risk management agency for the DIB (see Presidential Policy Directive 21 (PPD–21),[5] ''Critical Infrastructure Security and Resilience''). This program is aligned with the requirements of the Controlled Unclassified Information (CUI) program established in Executive Order 13556. Expanding eligibility requirements for the DIB CS Program will augment DoD's information sharing activities with the DIB.

Currently, the DIB CS Program has the following objectives:

- Establish a voluntary, mutually acceptable framework to protect information from unauthorized access.
- Protect the confidentiality of information exchanged to the maximum extent authorized by law.
- Create a trusted environment to maximize network defense and remediation efforts by:

1. Sharing cyber threat information and incident reports.
2. Providing mitigation/remediation strategies and malware analysis.

This program is part of DoD's larger portfolio of work to protect DoD information handled by the DIB by understanding and sharing information, building security partnerships, implementing long-term risk management programs, and maximizing efficient use of resources. It supports two-way information sharing and maintains meaningful relationships and frequent dialogue across the diverse array of eligible defense contractors. For eligible defense contractors, the program maintains a capability for companies to access classified government cyber threat information providing additional context to better understand the cyber threats targeting their networks and information systems.

In May 2012, DoD published an interim final rule establishing the voluntary DIB CS Program and the bilateral information sharing model still used today.[6] The 2012 rule established

[2] DIB CS Activities Security Classification Guide is available via *https://www.DTIC.mil.*

[4] *https://www.ecfr.gov/current/title-48/chapter-2/subchapter-H/part-252/subpart-252.2/section-252.204-7012.*

[5] *https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil.*

[6] 77 FR 27615, May 11, 2012 (*https://www.govinfo.gov/content/pkg/FR-2012-05-11/pdf/2012-10651.pdf*).

a voluntary cyber threat information sharing program for cleared defense contractors (CDC) with the ability to safeguard classified information, estimated at 2,650 in 2012. Under the rule CDC is defined as a private entity granted clearance by DoD to access, receive, or store classified information for the purpose of bidding for a contract or conducting activities in support of any program of DoD. The 2012 rule stated DoD would maintain a website to facilitate the following aspects of program participation: (1) sharing information regarding eligibility and participation in the program with potential participants, (2) applying to the program online, and 3) executing the necessary agreements with the Government. DoD has established this capability as an online portal referred to as ''DIBNet,'' located at *https://dibnet.dod.mil.* A final rule responding to public comments was published in October 2013.[7] In October 2015, responding to new statutory requirements for cyber incident reporting for DoD contractors, subcontractors, and those providing operationally critical support, DoD published another interim final rule[8] to expand eligibility to all cleared defense contractors (estimated at 8,500 in 2015 and 12,000 in 2022), subject to program eligibility requirements. The 2015 rule removed the requirement that CDCs be able to safeguard classified information to participate in the program. The rule also removed the mandatory program eligibility requirement to have or acquire a Communications Security (COMSEC) account[9] and obtain access to DoD's secure voice and data transmission systems, although participants still have to fulfill these requirements to receive classified cyber threat information electronically. A final rule responding to public comments was published in October 2016.[10]

Discussion of the Final Rule

With this rule, the Department is expanding eligibility requirements to allow greater program participation and increase the benefits of bilateral information sharing, which helps protect DoD controlled unclassified information from cyberattack, as well as to better align the voluntary DIB CS Program with DoD's mandatory cyber incident reporting requirements. The current eligibility requirements, based on the October 2016 rule, requires a company to be a cleared defense contractor[11] who:

- Has DoD-approved medium assurance certificates;[12]
- Has an existing facility clearance[13] to at least the Secret level; and
- Can execute the standardized Framework Agreement[14] provided to interested contractors after the Department has verified the DIB company is eligible.

The program has experienced steady growth, with the annual number of applications more than tripling since 2016 (80 total applications received in 2016, 266 total applications received in 2022). It has also seen a steady increase in the percentage of defense contractors who are interested in participating but do not meet current eligibility requirements. The percentage of applications received from ineligible defense contractors has risen at an average rate of 5% per year since 2016; 10% of applications received in 2016 were from ineligible defense contractors, while 45% of applicants in 2022 were ineligible. The steady increase in DIB applicants indicates an increasing desire amongst defense contractors to participate in a cyber threat information sharing program.

In addition, the Department has actively engaged defense associations, universities, and companies in the DIB, as well as participated in many public forums discussing cyber threats and the way forward. The overwhelming feedback was for the Department to facilitate engagement with the broader community of defense contractors beyond just the cleared defense community. In general, smaller defense contractors have fewer resources to devote to cybersecurity, which may provide a vector for adversaries to access information critical to national security. In addition, the Department is working on providing more tailored threat information to support the needs of a broader community of defense contractors with varying cybersecurity capabilities. The gap in eligibility in the current program, feedback from interested but ineligible contractors, a vulnerable DoD supply chain, and a pervasive cyber threat have prompted DoD to propose revising the eligibility requirements of the DIB CS Program to allow participation by non-cleared defense contractors.

The maximum number of defense contractors estimated to be subject to mandatory cyber incident reporting under DFARS clause 252.204–7012 is 80,000. The presence of the clause in a contract does not establish that covered defense information is shared. DoD is working on reporting mechanisms to better assess contractors managing covered defense information. The population of defense contractors in possession of covered defense information and subject to mandatory incident reporting requirements far exceeds the population of defense contractors currently eligible to participate in the voluntary DIB CS Program. With the changes to the eligibility criteria, an estimated additional 68,000 defense contractors will be eligible to participate in the voluntary DIB CS Program. Based on prior participation statistics, it is estimated that about 10% of the eligible contractors (12,000 + 68,000 = 80,000) will actually apply to join the voluntary DIB CS Program ($80{,}000 \times 0.10 = 8{,}000$).

Currently, the DIB CS Program has approximately 1,000 cleared defense contractors participating in the program. Program participants have access to technical exchange meetings, a collaborative web platform (DIBNet-U), and threat information products and services through the DoD Cyber Crime Center (DC3). DC3 implements the program's operations by sharing cyber threat information and intelligence with the DIB, and offering a variety of products, tools, services, and events. DC3 serves as the single clearinghouse for unclassified Mandatory Incident Reports (MIRs) and voluntary threat information sharing reports.

Changes to Definitions

In addition to the program eligibility changes described above, DoD is also finalizing the following changes.

[7] 78 FR 62430, October 22, 2013 (*https://www.govinfo.gov/content/pkg/FR-2013-10-22/pdf/2013-24256.pdf*).

[8] 80 FR 59581, October 2, 2015 (*https://www.govinfo.gov/content/pkg/FR-2015-10-02/pdf/2015-24296.pdf*).

[9] The National Security Agency administers COMSEC accounts.

[10] 81 FR 68312, October 4, 2016 (*https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23968.pdf*).

[11] 32 CFR 236.2 defines cleared defense contractor to mean a subset of contractors cleared under the National Industrial Security Program (NISP) who have classified contracts with the DoD.

[12] The DoD has established the External Certification Authority (ECA) program to support the issuance of DoD-approved certificates to industry partners and other external entities and organizations. The ECA program is designed to provide the mechanism for these entities to securely communicate with the DoD and authenticate to DoD Information Systems. [*https://public.cyber.mil/eca/*].

[13] Entities (including companies and academic institutions) engaged in providing goods or services to the U.S. Government involving access to or creation of classified information may be granted a Facility Clearance (FCL). The Defense Counterintelligence and Security Agency (DCSA) processes, issues, and monitors the continued eligibility of entities for an FCL. [*https://www.dcsa.mil/mc/isd/fc/*].

[14] Applicants to the DIB CS Program submit an application from *https://dibnet.dod.mil.* Once a company has been verified, the Framework Agreement is made available for review.

Section 236.2 Definitions

1. Access to media—This definition is being removed as it is no longer used in the rule text.

2. DIB CS Program participant—This definition has been revised to align with the revised eligibility requirements set forth in this final rule.

3. Government furnished information (GFI)—This definition was revised to adopt the convention of referring to the DIB CS Program with a capital 'P'.

Other Finalized Changes

DoD is amending § 236.4 (Mandatory cyber incident reporting procedures), in response to public comments received about the burden associated with medium assurance certificates. The amendment will require contractors to obtain PIEE account in conjunction with mandatory cyber incident reporting. This change will align the identity proofing processes used by DoD for the majority of DIB companies and will eliminate the cost associated with procuring medium assurance certificates. DoD will continue to accept medium assurance certificates to fulfil identity proofing requirements.

DoD is amending § 236.5 (DoD's DIB CS program) in order to align the program description with the revised eligibility requirements. As a result, references to cleared defense contractors have been replaced with contractors that own or operate a covered contractor information system. Security clearance information is only collected, when applicable, if a company elects and is eligible to participate in classified information sharing. In addition, the language stating participation is typically three to ten company-designated points of contact (POC) has been removed, to avoid confusion regarding the number of POCs, as some larger companies may wish to nominate a larger number of POCs and smaller companies may wish to nominate fewer.

DoD is amending § 236.7 (DoD's DIB CS program requirements) to remove the requirement that a company have an existing active facility clearance (FCL) to at least the Secret level granted under 32 CFR part 117, National Industrial Security Program Operating Manual (NISPOM),[15] to be eligible to participate in the DIB CS Program. In addition, references to cleared defense contractors have been replaced with contractors that own or operate a covered contractor information system.

A foundational element of the activities described in § 236.7 is the recognition that the information shared between DoD and DIB CS Program participants pursuant to the DIB CS Program includes CUI,[16] which requires protection. For additional information regarding the Government's safeguarding of information received from contractors that requires protection, see the Privacy Impact Assessment (PIA) for the DIB Cybersecurity Activities located at: *https://dodcio.defense.gov/Portals/0/Documents/DIB_PIA.pdf*. The PIA provides detailed procedures for handling personally identifiable information (PII), attributional information about the strengths or vulnerabilities of specific covered contractor information systems, information providing a perceived or real competitive advantage on future procurement action, and contractor information marked as proprietary or commercial or financial information. In addition, personnel information is covered by Office of the Secretary of Defense (OSD) System of Records Notice (SORN) DCIO 01 (*https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/OSDJS/DCIO-01.pdf*). No changes to the PIA or SORN are being made in conjunction with this final rule.

Expected Impact of the Final Rule

Comments were received on the cost of a DoD-approved medium assurance certificates and the accuracy of estimates relating to familiarization costs and attending meetings. DoD is removing the requirement for the DIB to have a DoD-approved medium assurance certificate to report cyber incidents. The requirement is being replaced with the requirement to register in PIEE which has established procedures to perform digital identity proofing. The basis for the cost estimate for a company to familiarize themselves with changes to this rule and determine if they would like to apply to the DIB CS Program does not include time for a company to perform an in-depth review of preexisting contractually mandated requirements. The basis for the cost estimate to participate in meetings uses the assumption a company sends the equivalent of an Information Security Analyst with the mean wage estimate published by the Bureau of Labor Statistics. If the company elects to send more senior representatives the cost will be higher. The economic analysis is being finalized without changes.

Costs

DoD believes the cost impact of the changes to this final rule is not significant, as the changes primarily expand the availability of the established DIB CS Program to additional defense contractors. The newly eligible population of defense contractors may incur costs to familiarize itself with the rule and those who elect to participate in the program will incur costs related to program participation. The Government will continue to incur costs related to operating the program. The DIB CS Program conducts outreach activities to defense contractors through press releases, participation in defense-oriented conferences, speaking engagements, and through digital media. The program will leverage pre-established channels to message changes to the program and engage with the eligible population of defense contractors. Based on the program growth experienced that during the last phase of program expansion the program is forecasting annual growth at just over 1% of the eligible population. At a growth rate of 1% per year it will take the program approximately 10 years to achieve the estimated 10% participation rate of the eligible DIB.

Costs to DIB Participants

In order to join the DIB CS Program there is an initial labor burden for a defense contractor to familiarize themselves with the rule and subsequently apply to the program and provide POC information. In total, if it takes each contractor 30 minutes to read and familiarize him/herself with the rule, it will take contractors 4,000 hours to familiarize themselves with the rule (8,000 participants x .5 = 4,000 hours). At an hourly wage of $108.92, the total cost incurred by contractors for rule familiarization will amount to $217,840 ($108.92 × .5 hours = $54.46 × 4,000 hours = $217,840). The hourly labor cost is based on the mean wage estimate from the Bureau of Labor Statistics for an Information Security Analysts, Occupational Employment and Wages, May 2021 and is covered under information collection 0704–0490. This hourly wage is adjusted upward by 100% to account for overhead and benefits, which implies a value of $108.92 per hour.

The estimated annual burden for a company to apply to the program or for a participating company to update POC information is $36.31, with a total annual cost to all participants of $319,498.67 at peak program participation. This calculation is based on 8,000 participants submitting an average of one application per year and 10% of the population (800 participants) submitting an update each year, with 20 minutes of labor per

[15] *https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-D/part-117.*

[16] *https://www.archives.gov/cui.*

submission, at a cost of $108.92 per hour ($108.92 × ⅓ hours = $36.31 × 8,800 events = $319,498.67).

There is an estimated annual burden projected at $1,089.20 for defense contractors voluntarily sharing cyber threat information. This is based on a defense contractor electing to submit an average of five informational reports per year with two hours of labor per voluntary submission, at a cost of $108.92 per hour ($108.92 × 2 hours = $217.84 × 5 reports = $1,089.20). It is estimated that 1% of the newly eligible population will elect to join the DIB CS Program annually, which currently has approximately 1,000 participants, with program growth plateauing at 10% of the population by Year 9. The table below shows the costs to industry to voluntarily sharing cyber threat information over a 9-year period. If, in the first year of the program expanding there are 980 participants and 800 new participants join the program, there will be a total of 1,780 participants. Assuming each participant responds five times, this totals 8,900 annual responses times $217.84 per response and will equal $1,938,776 in total annual cost to participants, which is covered in information collection 0704–0489.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
DIB CS Participants	1,780	2,580	3,380	4,180	4,980	5,780	6,580	7,380	8,000
Voluntary Reports Received	8,900	12,900	16,900	20,900	24,900	28,900	32,900	36,900	40,000
Annual Cost	$1,938,776	$2,810,136	$3,681,496	$4,552,856	$5,424,216	$6,295,576	$7,166,936	$8,038,296	$8,713,600

In addition, DIB CS Program participants may choose to attend meetings in conjunction with the DIB CS Program. All new participants are invited to attend an orientation session and all existing participants are invited to attend meetings on a quarterly basis. If a defense contractor chooses to send an employee to a day-long meeting each quarter, the defense contractor would incur a cost of $3,485.44 ($108.92 × 8 hours = $871.36 × 4 meetings = $3,485.44).

Costs to the Government

The DoD has identified general areas of costs related to the operation of this program. First, DoD incurs costs to implement this program operationally by responding to inquiries, processing application submissions and collecting, sharing, and managing POC information for program administration and management purposes. Second, DoD incurs costs to collect, analyze, and disseminate threat information.

DoD responds to an average of 2,000 questions each year and these responses are estimated to take 20 minutes per response. If it takes 20 minutes to respond to each question, it will take 667 hours to respond to questions. At an hourly wage of $51.16,[17] it will cost the DoD $34,107 dollars to respond to questions ($51.16 × (.333 × 2,000) = $34,107). Costs to the government are incurred when a company applies to the DIB CS Program to validate and store POC information and to perform follow-up activities with a company when the information is outdated. The processing time for these activities is estimated to be one hour per company.

If, by Year 9, 8,000 companies participate in the program and 10% of the companies update information with the program annually the labor cost to the government is expected to be $72,647.20 = (620 + 800 × $51.16).

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
DIB CS Participants	1780	2580	3380	4180	4980	5780	6580	7380	8000
New Applications ..	780	800	800	800	800	800	800	800	620
Updates	178	258	338	418	498	578	658	738	800
Annual Cost	$49,011.28	$54,127.28	$58,220.08	$62,312.88	$66,405.68	$70,498.48	$74,591.28	$78,684.08	$72,647.20

In addition, there is a cost incurred by the DoD to receive cyber threat information submitted by defense contractors to have it analyzed by cyber threat experts at DC3. By year 9 of the expanded program, it is estimated DC3 will receive 40,000 responses per year, based on the estimate that each participating company elects to submit 5 informational reports (8,000 participants × 5 reports). Each product takes approximately two hours to create and incurs an hourly labor cost of $51.16 per hour. This equals $102.32 (2 hours × 51.16) per response. The labor cost to the government is forecasted to be $4,092,800 annually after 9 years of growth. In addition to processing cyber threat information, the DoD incurs operational and maintenance costs for the system receiving and storing cyber threat information. This system costs the DoD $5,100,000 annually to maintain (covered under information collection 0704–0489).

Benefits

This program benefits the Department by increasing the overall security of the DIB through increasing awareness and improving assessments of cyber incidents that may affect mission critical capabilities and services. It continues to be an important element of the Department's comprehensive effort to defend DoD information, protect U.S. national interests against cyber-attacks, and support military operations and contingency plans worldwide. Once a

[17] This is based upon the 2022 General Schedule (GS) pay scale for a GS–9 Step 5 and is adjusted upward by 100% to adjust for overhead and benefits.

defense contractor joins the program, they are encouraged to share information, including cyber threat indicators, that they believe may be of value in alerting the Government and others, as appropriate, of adversary activity to enable the development of mitigation strategies and proactively counter threat actor activity. DC3 develops written products that include analysis of the threat, mitigations, and indicators of adversary activity. Even cyber incidents that are not compromises of covered defense information may be of interest to DoD for situational awareness purposes. This information is disseminated as anonymized threat products that are shared with authorized DoD personnel, other Federal agencies, and company-designated POCs participating in the DIB CS Program. With the revisions to the eligibility criteria, the Department will be able to reduce the impact of cyber threat activity on DIB networks and information systems and, in turn, preserve its technological advantage and protect DoD information and warfighting capabilities. The mitigation of the cyber threat targeting defense contractors reinforces the nation's national security and economic vitality.

For DIB participants, this program provides unique cyber threat information and technical assistance through analyst-to-analyst exchanges, mitigation and remediation strategies, and cybersecurity best practices in a collaborative environment. The shared unclassified and classified cyber threat information is used to bolster a company's cybersecurity posture and mitigate the growing cyber threat. The program's tailored support for small, mid-size, and large companies with varying cybersecurity maturity levels is an asset for participants. The program remains a key element of DoD's cybersecurity efforts by providing services to help protect DIB CS Program participants and the sensitive DoD information they handle.

Regulatory Compliance Analysis

A. Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Order 12866 directs agencies to assess all costs, benefits, and available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated ''significant,'' under Executive Order 12866.

B. Congressional Review Act (5 U.S.C. 801 et seq.)

Pursuant to the Congressional Review Act, this final rule has not been designated a major rule, as defined by 5 U.S.C. 804(2). This final rule will not have an economic effect above the $100 million threshold defined in 5 U.S.C. 804(2) or spur a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

C. Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Office of the DoD Chief Information Officer certified that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This final rule will have a significant positive impact on small entities that will become eligible to participate in and receive benefits through the DIB CS Program. For DIB participants, this program provides cyber threat information and technical assistance through analyst-to-analyst exchanges, mitigation and remediation strategies, and cybersecurity best practices in a collaborative environment. The shared threat information is used to bolster a company's cybersecurity posture and mitigate the growing cyber threat. The program's tailored support for small, mid-size, and large companies with varying cybersecurity maturity levels is an asset for participants, and in fact can avoid expending resources to obtain threat intelligence from private sources if the company elects to participate in services offered by the DoD that directly integrate threat intelligence.

Participation in the DIB CS Program is voluntary. Program application and participation costs are described in the cost analysis section of this final rule. These costs are voluntarily incurred and associated with the labor and resource costs to complete the required program paperwork, including execution of the Framework Agreement, to submit information to the Government, and to receive information from the Government. The costs associated with applying to the DIB CS Program are associated exclusively with labor costs and estimated to be $18.15 per company. None of the program's offering come at an additional fee to DIB participants and additional costs related to participation are estimated based on the time investment (labor hours) required to obtain the benefits as described in the cost analysis of this preamble. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

D. Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. When the Federal Government passes legislation requiring a State, local, or tribal government to perform certain actions or offer certain programs but does not include any funds for the actions or programs in the law, an unfunded mandate is the result. This final rule will not mandate any requirements for State, local, or tribal governments, and will not mandate private sector incurred costs above the $100 million threshold defined in 2 U.S.C. 1532.

E. Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

Section 236.2 of this rule contains information collection requirements. As required by the Paperwork Reduction Act (44 U.S.C. Chapter 35), DoD submitted information collection requests to the Office of Management and Budget for review and approval. In response to DoD's invitation in the proposed rule to comment on any potential paperwork burden associated with this rule, there were no comments from the public. This final rule contains the following information collection requirements under the Paperwork Reduction Act (PRA) of 1995.

- OMB Control Number 0704–0489, ''DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities Cyber Incident Reporting,''
- OMB Control Number 0704–0490, ''DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Points of Contact (POC) Information.''

The System of Records Notice associated with these information collections (DCIO 01, ''Defense Industrial Base (DIB) Cybersecurity (CS) Activities Records'') published on May

17, 2019. The **Federal Register** citation for the SORN is 84 FR 22477.

The Privacy Impact Assessment for the Defense Industrial Base (DIB) Cybersecurity (CS) Activities is posted at: *https://dodcio.defense.gov/Portals/0/Documents/DIB_PIA.pdf.*

F. Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This final rule will not have a substantial effect on State and local governments.

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

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or effects the distribution of power and responsibilities between the Federal Government and Indian tribes. This final rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 236

Government contracts, Security measures.

Accordingly, DoD amends 32 CFR part 236 as follows:

PART 236—DEPARTMENT OF DEFENSE (DoD) DEFENSE INDUSTRIAL BASE (DIB) CYBERSECURITY (CS) ACTIVITIES

■ 1. The authority citation for 32 CFR part 236 is revised to read as follows:

Authority: 10 U.S.C. 391, 393, and 2224; 44 U.S.C. 3506 and 3554; 50 U.S.C. 3330.

■ 2. Revise the heading of 32 CFR part 236 to read as set forth above.

■ 3. Revise and republish § 236.1 to read as follows:

§ 236.1 Purpose.

Cyber threats to contractor unclassified information systems represent an unacceptable risk of compromise of DoD information and pose an imminent threat to U.S. national security and economic security interests. This part requires all DoD contractors to rapidly report cyber incidents involving covered defense information on their covered contractor information systems or cyber incidents affecting the contractor's ability to provide operationally critical support. The part also permits eligible DoD contractors to participate in the voluntary DIB CS Program to share cyber threat information and cybersecurity best practices with DIB CS Program participants. The DIB CS Program enhances and supplements DIB CS Program participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems.

■ 4. Amend § 236.2 by:

■ a. Removing the definition of ''Access to media''.

■ b. Removing the definition of ''DIB participant'' and adding the definition ''DIB CS Program participant'' in its place.

■ c. Removing the words ''DIB CS program'' in the definition of ''Government furnished information (GFI)'' and adding in their place the words ''DIB CS Program''.

The addition reads as follows:

§ 236.2 Definitions.

* * * * *

DIB CS Program participant means a contractor that has met all of the eligibility requirements to participate in the voluntary DIB CS Program as set forth in this part (see § 236.7).

* * * * *

§ 236.3 [Amended]

■ 5. Amend § 236.3 by:

■ a. Removing the word ''program'' and adding in its place the words ''Program participants'' in paragraph (b)(1).

■ b. Removing the words ''DIB CS program'' and adding in their place the words ''DIB CS Program'' in paragraph (c).

■ 6. Amend § 236.4 by:

■ a. Removing the text ''*http*'' and adding in its place the text ''*https*'' in paragraphs (b)(2), (c), and (d).

■ b. Revising paragraphs (e) through (g).

■ c. Removing the words ''paragraph (e)'' and adding in their place the words ''paragraph (i)'' in paragraph (k).

■ d. Revising paragraph (m)(4).

■ e. Adding a heading for paragraph (o).

■ f. Revising paragraph (p).

The revisions and additions read as follows:

§ 236.4 Mandatory cyber incident reporting procedures.

* * * * *

(e) *Procurement Integrated Enterprise Environment (PIEE) account requirement.* To report cyber incidents in accordance with this section, the contractor or subcontractor shall have a PIEE account to access *https://dibnet.dod.mil.* For information on obtaining a PIEE account, see *https://piee.eb.mil/.*

(f) *Third-party service provider support.* If the contractor utilizes a third-party service provider (SP) for information system security services, the contractor may authorize the SP to report cyber incidents on behalf of the contractor.

(g) *Voluntary information sharing.* Contractors are encouraged to report information to promote sharing of cyber threat indicators that they believe are valuable in alerting the Government and others, as appropriate, in order to better counter threat actor activity. Cyber incidents that are not compromises of covered defense information or do not adversely affect the contractor's ability to perform operationally critical support may be of interest to the DIB and DoD for situational awareness purposes.

* * * * *

(m) * * *

(4) For national security purposes, including cyber situational awareness and defense purposes (including sharing non-attributional cyber threat information with defense contractors participating in the DIB CS Program authorized by this part); or

* * * * *

(o) *Contractor activities.* * * *

(p) *Freedom of Information Act (FOIA).* Agency records, which may include qualifying information received from non-Federal entities, are subject to request under the Freedom of Information Act (5 U.S.C. 552). The Government will notify the non-Government source or submitter (*e.g.,* contractor or DIB CS Program participant) of the information in accordance with the procedures in 32 CFR 286.10.

* * * * *

■ 7. Revise and republish § 236.5 to read as follows:

§ 236.5 DoD's DIB CS Program.

(a) All defense contractors that meet the requirements set forth in § 236.7 are eligible to join the DIB CS Program as a DIB CS Program participant. Defense contractors meeting the additional eligibility requirements in § 236.7 can elect to access and receive classified information electronically.

(b) Under the voluntary activities of the DIB CS Program, the Government and each DIB CS Program participant will execute a standardized agreement, referred to as a Framework Agreement (FA) to share, in a timely and secure manner, on a recurring basis, and to the greatest extent possible, cybersecurity information.

(c) Each such FA between the Government and a DIB CS Program participant must comply with and

implement the requirements of this part, and will include additional terms and conditions as necessary to effectively implement the voluntary information sharing activities described in this part with individual DIB CS Program participants.

(d) DoD's DIB CS Program Management Office is the overall point of contact for the program. The DC3 managed DoD–DIB Collaborative Information Sharing Environment (DCISE) is the operational focal point for cyber threat information sharing and incident reporting under the DIB CS Program.

(e) The Government will maintain a website or other internet-based capability to provide potential DIB CS Program participants with information about eligibility and participation in the program, to enable online application or registration for participation, and to support the execution of necessary agreements with the Government.

(f) As participants of the DIB CS Program, defense contractors are encouraged to share cyber threat indicators and information that they believe are valuable in alerting the Government and other DIB CS Program participants to better counter threat actor activity. Cyber activity that is not covered under § 236.4 may be of interest to DIB CS Program participants and DoD.

(g) The Government shall share GFI DIB CS Program participant or designated SP in accordance with this part.

(h) Prior to receiving GFI, each DIB CS Program participant shall provide the requisite points of contact information, to include U.S. citizenship and security clearance information, as applicable, for the designated personnel within their company in order to facilitate the DoD–DIB interaction in the DIB CS Program. The Government will confirm the accuracy of the information provided as a condition of that point of contact being authorized to act on behalf of the DIB CS Program participant for this program.

(i) GFI will be issued via both unclassified and classified means. DIB CS Program participants handling and safeguarding of classified information shall be in compliance with 32 CFR part 117. The Government shall specify transmission and distribution procedures for all GFI, and shall inform DIB CS Program participants of any revisions to previously specified transmission or procedures.

(j) Except as authorized in this part or in writing by the Government, DIB CS Program participants may:

(1) Use GFI only on U.S. based covered contractor information systems, or U.S. based networks or information systems used to provide operationally critical support; and

(2) Share GFI only within their company or organization, on a need-to-know basis, with distribution restricted to U.S. citizens.

(k) In individual cases DIB CS Program participants may request, and the Government may authorize, disclosure and use of GFI under applicable terms and conditions when the DIB CS Program participant can demonstrate that appropriate information handling and protection mechanisms are in place and has determined that it requires the ability:

(1) To share the GFI with a non-U.S. citizen; or

(2) To use the GFI on a non-U.S. based covered contractor information system; or

(3) To use the GFI on a non-U.S. based network or information system in order to better protect a contractor's ability to provide operationally critical support.

(l) DIB CS Program participants shall maintain the capability to electronically disseminate GFI within the Company in an encrypted fashion (*e.g.,* using Secure/Multipurpose internet Mail Extensions (S/MIME), secure socket layer (SSL), Transport Layer Security (TLS) protocol version 1.2, DoD-approved medium assurance certificates).

(m) DIB CS Program participants shall not share GFI outside of their company or organization, regardless of personnel clearance level, except as authorized in this part or otherwise authorized in writing by the Government.

(n) If the DIB CS Program participant utilizes a SP for information system security services, the DIB CS Program participant may share GFI with that SP under the following conditions and as authorized in writing by the Government:

(1) The DIB CS Program participant must identify the SP to the Government and request permission to share or disclose any GFI with that SP (which may include a request that the Government share information directly with the SP on behalf of the DIB CS Program participant) solely for the authorized purposes of this program.

(2) The SP must provide the Government with sufficient information to enable the Government to determine whether the SP is eligible to receive such information, and possesses the capability to provide appropriate protections for the GFI.

(3) Upon approval by the Government, the SP must enter into a legally binding agreement with the DIB CS Program participant (and also an appropriate agreement with the Government in any case in which the SP will receive or share information directly with the Government on behalf of the DIB CS Program participant) under which the SP is subject to all applicable requirements of this part and of any supplemental terms and conditions in the DIB CS Program participant's FA with the Government, and which authorizes the SP to use the GFI only as authorized by the Government.

(o) The DIB CS Program participant may not sell, lease, license, or otherwise incorporate the GFI into its products or services, except that this does not prohibit a DIB CS Program participant from being appropriately designated an SP in accordance with paragraph (n) of this section.

■ 8. Revise and republish § 236.6 to read as follows:

§ 236.6 General provisions of DoD's DIB CS Program.

(a) Confidentiality of information that is exchanged under the DIB CS Program will be protected to the maximum extent authorized by law, regulation, and policy. DoD and DIB CS Program participants each bear responsibility for their own actions under the voluntary DIB CS Program.

(b) All DIB CS Program participants may participate in the Department of Homeland Security's Enhanced Cybersecurity Services (ECS) program (*https://www.cisa.gov/resources-tools/programs/enhanced-cybersecurity-services-ecs*).

(c) Participation in the voluntary DIB CS Program does not obligate the DIB CS Program participant to utilize the GFI in, or otherwise to implement any changes to, its information systems. Any action taken by the DIB CS Program participant based on the GFI or other participation in this program is taken on the DIB CS Program participant's own volition and at its own risk and expense.

(d) A DIB CS Program participant's participation in the voluntary DIB CS Program is not intended to create any unfair competitive advantage or disadvantage in DoD source selections or competitions, or to provide any other form of unfair preferential treatment, and shall not in any way be represented or interpreted as a Government endorsement or approval of the DIB CS Program participant, its information systems, or its products or services.

(e) The DIB CS Program participant and the Government may each unilaterally limit or discontinue participation in the voluntary DIB CS Program at any time. Termination shall

not relieve the DIB CS Program participant or the Government from obligations to continue to protect against the unauthorized use or disclosure of GFI, attribution information, contractor proprietary information, third-party proprietary information, or any other information exchanged under this program, as required by law, regulation, contract, or the FA.

(f) Upon termination of the FA, change of status as a defense contractor, and/or change of Facility Security Clearance (FCL) status below Secret, GFI must be returned to the Government or destroyed pursuant to direction of, and at the discretion of, the Government.

(g) Participation in these activities does not abrogate the Government's, or the DIB CS Program participants' rights or obligations regarding the handling, safeguarding, sharing, or reporting of information, or regarding any physical, personnel, or other security requirements, as required by law, regulation, policy, or a valid legal contractual obligation. However, participation in the voluntary activities of the DIB CS Program does not eliminate the requirement for DIB CS Program participants to report cyber incidents in accordance with § 236.4.

■ 9. Revise § 236.7 to read as follows:

§ 236.7 DoD's DIB CS Program requirements.

(a) To participate in the DIB CS Program, a contractor must own or operate a covered contractor information system and shall execute the standardized FA with the Government (available during the application process), which implements the requirements set forth in §§ 236.5 and 236.6.

(b) In order for DIB CS Program participants to receive classified cyber threat information electronically, the company must be a cleared defense contractor and must:

(1) Have an existing active facility clearance level (FCL) to at least the Secret level in accordance with 32 CFR part 117;

(2) Have or acquire a Communication Security (COMSEC) account in accordance with 32 CFR part 117, which provides procedures and requirements for COMSEC activities;

(3) Have or acquire approved safeguarding for at least Secret information, and continue to qualify under 32 CFR part 117 for retention of its FCL and approved safeguarding; and

(4) Obtain access to DoD's secure voice and data transmission systems supporting the voluntary DIB CS Program.

Dated: March 1, 2024.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–04752 Filed 3–11–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2023–OS–0060]

RIN 0790–AL64

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense (OSD), Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Department of Defense (Department or DoD) is issuing a final rule to amend its regulations to exempt portions of the system of records titled DoD–0019, ''Information Technology Access and Audit Records,'' from certain provisions of the Privacy Act of 1974.

DATES: This rule is effective on March 12, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, Privacy and Civil Liberties Directorate, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Department of Defense, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700; *OSD.DPCLTD@mail.mil;* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

Discussion of Comments and Changes

The proposed rule published in the **Federal Register** (88 FR 60411–60413) on September 1, 2023. Comments were accepted for 60 days until October 31, 2023. No comments were received.

I. Background

In finalizing this rule, DoD is exempting portions of this system of records titled, DoD–0019, ''Information Technology Access and Audit Records,'' from certain provisions of the Privacy Act of 1974. The purpose of this system of records is to support information systems being established within the DoD using the same categories of data for the same purposes. This system of records covers DoD's maintenance of records related to requests for user access, attempts to access, granting of access, records of user actions for DoD information technology (IT) systems, and user agreements. This includes details of programs, databases, functions, and sites accessed and/or used, and the information products created, received, or altered during the use of IT systems. The system consists of both electronic and paper records and will be used by DoD components and offices to maintain records about individuals who have user agreements, user access to and activity on networks, computer systems, applications, databases, or other digital technologies.

II. Privacy Act Exemption

The Privacy Act allows Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including those that provide individuals with a right to request access to and amendment of their own records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process pursuant to 5 U.S.C. 553(b)(1)–(3), (c), and (e). The OSD is amending 32 CFR part 310 to add a new Privacy Act exemption rule for this system of records. The DoD is adding exemptions for this system of records pursuant to 5 U.S.C. 552a(k)(1) and (2) because some of its records may contain classified national security information or investigatory material compiled for law enforcement purposes. The DoD is claiming an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain recordkeeping and notice requirements, to avoid, among other harms, frustrating the underlying purposes for which the information was gathered.

Regulatory Analysis

Executive Order 12866—Regulatory Planning and Review; Executive Order 13563—Improving Regulation and Regulatory Review; and Executive Order 14094—Modernizing Regulatory Review

Executive Orders 12866 (as amended by Executive Order 14094) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action under these Executive orders.

Congressional Review Act

The Congressional Review Act (5 U.S.C. 801 *et seq.*) generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. DoD will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule may take effect no earlier than 60 calendar days after Congress receives the rule report or the rule is published in the **Federal Register**, whichever is later. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4; 2 U.S.C. 1532(a)) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates may result in the expenditure by State, local and Tribal governments in the aggregate, or by the private sector, in any one year of $100 million in 1995 dollars, updated annually for inflation. This rule will not mandate any requirements for State, local, or Tribal governments, nor will it affect private sector costs.

Regulatory Flexibility Act

The Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency has certified that this rule is not subject to the Regulatory Flexibility Act (Pub. L. 96–354; 5 U.S.C. 601 *et seq.*) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule is concerned only with the administration of Privacy Act systems of records within the DoD. Therefore, the Regulatory Flexibility Act, as amended, does not require DoD to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (Pub. L. 96–511; 44 U.S.C. 3501 *et seq.*) was enacted to minimize the paperwork burden for individuals; small businesses; educational and nonprofit institutions; Federal contractors; State, local and Tribal governments; and other persons resulting from the collection of information by or for the Federal Government. The Act requires agencies to obtain approval from the Office of Management and Budget before using identical questions to collect information from ten or more persons. This rule does not impose reporting or recordkeeping requirements on the public.

Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that has federalism implications, imposes substantial direct requirement costs on State and local governments, and is not required by statute, or has federalism implications and preempts State law. This rule will not have a substantial effect on State and local governments.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on one or more Indian Tribes, preempts Tribal law, or affects the distribution of power and responsibilities between the Federal Government and Indian Tribes. This rule will not have a substantial effect on Indian Tribal governments.

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

PART 310—PROTECTION OF PRIVACY AND ACCESS TO AND AMENDEMENT OF INDIVIDUAL RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Amend § 310.13 by adding paragraph (e)(14) to read as follows:

§ 310.13 Exemptions for DoD-wide systems.

* * * * *

(e) * * *

(14) *System identifier and name.* DoD–0019, ''Information Technology Access and Audit Records.''

(i) *Exemptions.* This system of records is exempt from 5 U.S.C. 552a (c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and(I); and (f).

(ii) *Authority.* 5 U.S.C. 552a(k)(1) and (2).

(iii) *Exemption from the particular subsections.* Exemption from the particular subsections is justified for the following reasons:

(A) *Subsections (c)(3), (d)(1), and (d)(2)—*(*1*) *Exemption (k)(1).* Records in this system of records may contain information that is properly classified pursuant to executive order. Application of exemption (k)(1) may be necessary because access to and amendment of the records, or release of the accounting of disclosures for such records, could reveal classified information. Disclosure of classified records to an individual may cause damage to national security.

(*2*) *Exemption (k)(2).* Records in this system of records may contain investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2). Application of exemption (k)(2) may be necessary because access to, amendment of, or release of the accounting of disclosures of such records could: inform the record subject of an investigation of the existence, nature, or scope of an actual or potential law enforcement or disciplinary investigation, and thereby seriously impede law enforcement efforts by permitting the record subject and other persons to whom he might disclose the records or the accounting of records to avoid criminal penalties, civil remedies, or disciplinary measures; interfere with a civil or administrative action or investigation by allowing the subject to tamper with witnesses or evidence, and to avoid detection or apprehension, which may undermine the entire investigatory process; reveal confidential sources who might not have otherwise come forward to assist in an investigation and thereby hinder DoD's ability to obtain information from future confidential sources; and result in an unwarranted invasion of the privacy of others. Amendment of such records could also impose a highly impracticable administrative burden by requiring investigations to be continuously reinvestigated.

(B) *Subsections (d)(3) and (4).* These subsections are inapplicable to the extent an exemption is claimed from subsections (d)(1) and (2). Accordingly, exemptions from subsections (d)(3) and (4) are claimed pursuant to (k)(1) and (2).

(C) *Subsection (e)(1).* Additionally, records within this system may be properly classified pursuant to executive order. The collection of information pertaining to the use of government information technology and data systems may include classified records, and it is not always possible to conclusively determine the relevance and necessity of such information in the early stages of a collection. In some instances, it will be only after the collected information is evaluated in light of other information that its relevance and necessity can be assessed. Further, disclosure of classified records

to an individual may cause damage to national security. Additionally, in the collection of information for investigatory or law enforcement purposes it is not always possible to conclusively determine the relevance and necessity of particular information in the early stages of the investigation or adjudication. In some instances, it will be only after the collected information is evaluated in light of other information that its relevance and necessity for effective investigation and adjudication can be assessed. Collection of such information permits more informed decision-making by the Department when making required investigatory or law enforcement determinations. Accordingly, application of exemptions (k)(1) and (2) may be necessary.

(D) *Subsections (e)(4)(G) and (H).* These subsections are inapplicable to the extent exemption is claimed from subsections (d)(1) and (2).

(E) *Subsection (e)(4)(I).* To the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect national security, the confidentiality of sources of information and to protect the privacy and physical safety of witnesses and informants. Accordingly, application of exemptions (k)(1) and (2) may be necessary.

(F) *Subsection (f).* The agency's rules are inapplicable to those portions of the system that are exempt. Accordingly, application of exemptions (k)(1) and (2) may be necessary.

(iv) *Exempt records from other systems.* In the course of carrying out the overall purpose for this system, exempt records from other systems of records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

Dated: March 6, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–05142 Filed 3–11–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0155]

RIN 1625–AA00

Safety Zone; Gulf of Mexico and South Bay, Boca Chica Beach, TX

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

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones to protect personnel, vessels, and the marine environment from potential hazards created by commercial spaceflight activities. One safety zone is in the navigable waters of South Bay, TX and the other is in the navigable waters of the Gulf of Mexico, within 12 nautical miles. Entry of vessels or persons into these zones are prohibited unless specifically authorized by the Captain of the Port, Sector Corpus Christi (COTP) or a designated representative.

DATES: This rule is effective from March 14, 2024 through March 26, 2024, and subject to enforcement between the hours of 6 a.m. to noon, each day.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0155 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander Anthony Garofalo, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email *Anthony.M.Garofalo@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to 5 U.S.C. 553(b). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. Space Exploration Technologies Corporation (SpaceX) will begin operation of its Starship/Super Heavy launch operations on March 14, 2024, through March 26, 2024, each day. There is insufficient time between now and then to provide notice of a proposal to create these safety zones, consider comments received, and publish a final rule.

In addition, the Coast Guard finds that good cause also exists under 5 U.S.C. 553(d)(3) for making this rule effective less than 30 days after publication in the **Federal Register** because the safety zones must be in effect in fewer than 30 days to serve their purpose and it would be contrary to the public interest to delay their effective date until after the hazardous activities begin.

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 Corpus Christi (COTP) has determined that hazards inherent in rocket launching activity necessitate provisions to protect personnel, vessels, and the marine environment while it is taking place. The hazards inherent in SpaceX's rocket launching activities include free falling debris and/or descending vehicles or vehicle components.

IV. Discussion of the Rule

This rule is subject to enforcement from 6 a.m. to noon each day, from March 14, 2024, through March 26, 2024. No vessel or person will be permitted to enter the temporary safety zones during the period in which the rule is subject to enforcement without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450. The Coast Guard will issue Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866, 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, and duration of the safety zones. The safety zones cover approximately 4.5 square mile area of the South Bay and approximately 115 square mile area of the Gulf of Mexico offshore Boca Chica, Beach, TX. The temporary safety zones will be subject to enforcement for a period of 6 hours a day, from March 14, 2024, through March 26, 2024. The rule does not completely prohibit vessel traffic within the waterway and it allows mariners to request permission to enter the zones.

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 temporary safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

This rule 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

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 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 establishment of two temporary safety zones for navigable waters in the Gulf of Mexico and South Bay. The safety zones are needed to protect personnel, vessels, and the marine environment from potential hazards created by rocket launching activity that may include free falling debris and/or descending vehicles or vehicle components under various means of control. It is categorically excluded from further review under paragraph L60(c), in Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

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

List of Subjects in 33 CFR Part 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.T08–0155 to read as follows:

§ 165.T08–0155 Safety Zones; Gulf of Mexico and South Bay, Boca Chica Beach, TX.

(a) *Location.* The following areas are safety zones: Safety Zone A consists of all navigable waters of the Gulf of Mexico, from the surface to bottom, encompassed by a line connecting the

following points beginning at Point 1: 26°2′36″ N 097°9′8″ W, thence to Point 2: 26°3′0″ N 097°7′0″ W, thence to Point 3: 26°7′48″ N 096°56′2.2″ W, thence following the 12NM line to United States of America/Mexico Maritime Boundary Line, thence following the United States of America/Mexico Maritime Boundary Line to Point 4: 25°57′24.2″ N 097°8′49″ W, thence following the coast to Point 1. Safety Zone B consists of all navigable waters of South Bay, from the surface to bottom, encompassed by a line connecting the following points beginning at Point 5: 26°2′45″ N 097°11′6.3″ W, thence to Point 6: 26°2′45″ N 097°10′53.4″ W, thence following the coastline to Point 5. These coordinates are based on World Geodetic System (WGS) 84.

(b) *Enforcement period.* This section will be subject to enforcement from 6 a.m. to noon on each day, from March 14, 2024, through March 26, 2024.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into these temporary safety zones are prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. They may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450.

(2) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate.

Dated: March 6, 2024.

Jason Gunning,

Captain, U.S. Coast Guard, Captain of the Port, Sector Corpus Christi.

[FR Doc. 2024–05205 Filed 3–11–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2023–OELA–0132]

Final Priorities, Requirements, and Definitions—National Professional Development Program

AGENCY: Office of English Language Acquisition, Department of Education.

ACTION: Final priorities, requirements, and definitions.

SUMMARY: The Department of Education (Department) establishes these final priorities, requirements, and definitions for use in the National Professional Development (NPD) program, Assistance Listing Number 84.365Z. The Department may use one or more of these priorities, requirements, and definitions for competitions in fiscal year (FY) 2024 and later years. We intend for these priorities, requirements, and definitions to increase the number of bilingual and multilingual teachers supporting English learners (ELs).

DATES: These priorities, requirements, and definitions are effective April 11, 2024.

FOR FURTHER INFORMATION CONTACT: Francisco Javier López, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Telephone: (202) 558–4880. Email: *Francisco.Javier.Lopez@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The NPD program, authorized by sections 3111(c)(1)(C) and 3131 of the ESEA, provides grants to IHEs or public or private entities with relevant experience and capacity, in consortia with State educational agencies (SEAs) or local educational agencies (LEAs), to implement pre-service and in-service professional development activities intended to improve instruction for ELs and assist education personnel working with ELs to meet high professional standards.

Program Authority: 20 U.S.C. 6861.

We published a notice of proposed priorities, requirements, and definitions (NPP) for this program in the **Federal Register** on September 15, 2023 (88 FR 63543). The NPP contained background information and our reasons for proposing the priorities, requirements, and definitions. As discussed in the *Analysis of Comments and Changes* section of this document, we revised the definition of ''pre-service'' to ensure that GYO programs are part of, and aligned with, State-approved, State-registered pre-service programs. In addition, we added a priority (Final Priority 2) to specifically address the recruitment, preparation, and retention needs of emergent bilingual or multilingual teacher candidates (*i.e.,* not yet bilingual or multilingual, or not yet fully licensed or certified as a teacher, or both) and adjusted the numbering of the priorities accordingly. Next, we revised Priority 4 (formerly Proposed Priority 3) to include school leaders and individuals who are pursuing an additional credential to work in a multilingual setting. Additionally, we consolidated the strategies in Final Priority 1 along with clarifying that the term ''evidence-based'' in Final Priorities 1, 2, and 4 is as defined in 34 CFR 77.1(c). Finally, we simplified the definition of ''low-income'' for clarity and opted for the term ''student from a low-income background'' instead of ''low-income student'' as well as clarified the definition of ''bilingual or multilingual.''

Public Comment: In response to our invitation in the NPP, 35 parties submitted comments addressing the proposed priorities, requirements, and definitions. We group major issues according to subject. Generally, we do not address technical and other minor changes or suggested changes that the law does not authorize us to make under the applicable statutory authority.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priorities, requirements, and definitions since publication of the NPP follows.

General Comments

Comment: Eighteen commenters expressed support for the Department's efforts to meet the needs of our Nation's multilingual students by addressing the teacher shortage. Many of these commenters applauded the Department's emphasis on GYO strategies. Several commenters noted the timeliness of the proposed priorities and the Secretary's Raise the Bar initiative. More specifically, a couple of commenters emphasized the need for such pre-service programs while others emphasized the importance of the in-service training articulated in Final Priority 4.

Discussion: We appreciate the support for the NPD program and for the specific emphasis on increasing the numbers of bilingual and multilingual teachers, specifically through GYO strategies, improving instruction for ELs, and promoting pathways to multilingualism for all students.

Changes: None.

Comment: Three commenters offered broad strategies for the Department and the field to consider, noting the importance of incentives to encourage participation. One of these commenters expressed the importance of incentivizing participation specifically in GYO programs. In addition, this commenter detailed numerous strategies to address the shortage of multilingual teachers. Two of the three commenters recommended that the Department provide targeted incentives for current

teachers to pursue and obtain bilingual certifications.

Discussion: The Department appreciates the suggestions for increasing the number of bilingual or multilingual teachers and recognizes the importance of incentives to encourage participation in teacher professional development programs. The NPD program allows for projects that incentivize participation through preparation stipends and tuition payments.

Changes: None.

Comment: One commenter agreed that, to provide an equitable education to students, it is critical to increase the number of teachers with bilingual or ESL certification. Two commenters highlighted the importance of ensuring equitable access to bilingual opportunities for emergent bilingual students and children with disabilities. One of these commenters offered several suggestions, including incentivizing schools to create policies to honor emergent bilingual students' multilingualism with the seal of biliteracy and incentivizing teachers to pursue dual certification in bilingual education and special education to improve bilingual services for emergent bilingual students with disabilities.

Discussion: We appreciate these comments and have designed these priorities with the goal of expanding pathways to multilingualism for all students, including English learner students and students with disabilities. While this regulatory action does not focus specifically on special education, applications that incorporate opportunities for certification in bilingual education for special education candidates are allowable and encouraged in the NPD program.

Changes: None.

Comment: One commenter highlighted the distinction between the terms ''bilingual educator'' and ''English language learner teacher'' with regards to the way instruction is delivered.

Discussion: We appreciate this comment and recognize that the language used to describe educators and students in the field of multilingual and English learner education varies.

Changes: None.

Comment: One commenter noted the challenge to effective multilingual education due to teachers having large caseloads of students and recommended imposing a cap on teachers' caseloads.

Discussion: While we acknowledge the commenter's suggestion that there should be a Federal cap on caseloads, which we interpret to mean class size, we are unable to establish Federal requirements that are beyond the scope of the statutory authority for Department programs and therefore have not added the requested cap to this rule.

Changes: None.

Comment: One commenter recommended increasing teacher salaries and establishing regulations on the number of hours teachers work beyond the educational day. In addition, this commenter suggested that schools provide more supplies and other resources.

Discussion: We recognize the importance of teacher salaries and workloads and encourage states to ensure that all teachers are paid a livable and competitive wage. However, we are unable to establish Federal requirements beyond the scope of the statutory authority for Department programs.

Changes: None.

Comment: One commenter proposed recommendations for improving the number and quality of qualified bilingual and multilingual programs/classes in their State.

Discussion: We appreciate this comment. However, the systems and structures at the State and district levels that were recommended are beyond the scope of the statutory authority of this Federal program.

Changes: None.

Comment: One commenter detailed their organization's efforts and support for GYO programs designed to increase the number of multilingual teachers via various pathways.

Discussion: We appreciate the work of the commenter to address the shortage of multilingual teachers.

Changes: None.

Comment: Two commenters urged funding for in-service English as a Second Language (ESL) teachers as well as the school districts who employ them to promote bilingualism, particularly advocating for increased language opportunities for teachers who only speak English. The commenters also shared that support should be directed towards enhancing literacy instruction.

Discussion: The Department thanks the commenters for these suggestions and recognizes the importance of in-service training. There is already an established NPD priority for projects that provide in-service professional development to improve instruction for ELs. This is inclusive of all educators who work with ELs. We agree with the importance of literacy instruction but do not think it is necessary to prescribe specific content areas within the priorities. We believe that applicants should propose the content areas they believe will best prepare education personnel who are serving ELs, such as literacy instruction.

Changes: None.

Comment: One commenter suggested requirements for entities offering accredited pre-service training programs, including that the programs be specialized according to content area and be composed of at least 18 hours of training to prepare teachers to support linguistically diverse students. In addition, this commenter stated that SEAs and LEAs need models and guidance for supporting newcomer students and migratory youth, and the commenter highlighted benefits of universal bilingual kindergarten.

Discussion: We recognize the importance of teacher preparation and programs that provide teachers with the skills needed to support classrooms that include students who speak multiple languages and students with varying levels of language proficiency in these languages. We appreciate the commenter's suggestions for supporting newcomer students and migratory youth and the support for early childhood education. Rather than prescribing specific types of instruction for pre-service training programs, we encourage applicants to propose programs that are evidence-based and that will best prepare education personnel who are serving ELs.

Changes: None.

Comment: Five commenters explained the importance of supporting educational programs in rural communities where there are a growing number of multilingual and English learner students. Three of these commenters suggested that the NPD program incorporate a priority for bilingual and multilingual educators in rural school districts. One of these commenters expressed concern that peer reviewers from past competitions were not aware of the needs of rural communities.

Discussion: We appreciate the commenters' recommendation to support rural communities and recognize the growing number of multilingual and EL students attending schools in rural communities. Eligible rural-serving entities are encouraged to apply for NPD program grants. The Department offers a variety of supports for all applicants, including those who have not received an NPD program grant in prior years. For example, the Department offers a pre-application webinar and responds to questions as part of every NPD competition. The Department also provides more general resources that are available to entities applying for any grant program. Please see *https://www2.ed.gov/fund/grant/*

about/discretionary/index.html. We did not create a new priority or expand an existing priority to focus on rural communities in the final priorities because there is an administrative priority for rural applicants (85 FR 13640) [1] that remains in effect and is available for use by the NPD program. Finally, the Department's procedures for awarding discretionary grants include a variety of safeguards and technical assistance to ensure fair grant competitions. For example, for almost all the Department's grant competitions, program staff recruit application reviewers from outside the Federal Government. Peer reviewers for the NPD program are recruited and selected based on their qualifications and experience in serving EL students. And, while Department staff screen applications to ensure that they meet all program requirements, the non-Federal reviewers read and independently score the applications assigned to them.

Changes: None.

Comment: Two commenters noted the importance of training multilingual teachers for children aged five and under. One of these commenters asked that we expand Priority 1 to specifically include early childhood educators. The second commenter advocated for making Proposed Priorities 1 and 3 (Final Priorities 1 and 4) absolute priorities and weighting Proposed Priority 2 (Final Priority 3) heavily as a competitive preference priority.

Discussion: The Department appreciates the support of these commenters and shares the belief in the importance of expanding the number of bilingual and multilingual educators supporting early learning. We encourage applications that incorporate training for bilingual and multilingual teachers on how best to support children aged five and under. In general, we believe this type of training is allowable under Final Priorities 1, 2, and 4. Therefore, we do not believe it is necessary to modify the priorities or requirements. We think it is important to allow flexibility for applicants to propose projects they believe will best prepare teacher candidates for serving ELs and based on the need at the time.

Details about future competitions, including absolute and competitive preference priorities, will be published in the **Federal Register** in future notices inviting applications.

Changes: None.

Comment: One commenter, writing on behalf of their association, explained the importance of supporting students and educators from Latino backgrounds. This commenter specifically advocated for Proposed Priority 3 (Final Priority 4), stating that it would help eliminate the educator shortage, increase services for students who are ELs, and expand pathways to multilingualism for all students.

Discussion: We appreciate the commenter's recommendations to ensure that the priorities and strategies for the NPD program address the unique considerations of specific linguistic and cultural communities, and we acknowledge the commenter's support for Proposed Priority 3 (Final Priority 4). Because the NPD program is statutorily authorized to serve all ELs, and we intend for the final priorities, requirements, and definitions to expand capacity to support culturally and linguistically diverse students and educators, we have not changed the priorities to focus explicitly on specific communities.

Changes: None.

Comment: Two commenters highlighted that consideration should be made for varying language proficiency within certain contexts, particularly within specific languages and populations, such as indigenous and refugee communities. One of the commenters advised that there may be certain languages where there may not be a large population of advanced speakers, and some advanced speakers may not have advanced proficiency in all domains of the language. A second commenter advocated for targeted programming and support for Native American languages as defined in section 104 of the Native American Language Act of 1990 (NALA 1990) and in ESEA sections 3127 and 3124(3). Both commenters made specific recommendations for the explicit inclusion of Native American languages within the priorities and an adjustment of the definition of ''bilingual or multilingual'' to allow for various levels of proficiency for Native American languages. Finally, the second commenter also recommended allowing projects to support teacher candidates' language development in Native American languages given that many Native American languages have declining numbers of individuals who are highly proficient.

Discussion: We recognize the importance of strengthening and revitalizing Native American languages through the recruitment, retention, and empowerment of Native American educators, and encourage projects designed to foster a high level of proficiency in Native American languages. The Department is actively supporting Native American language revitalization through this and other programs.

The NPD program is designed to support professional development for educators working with ELs who speak all languages, including Native American languages as defined by NALA 1990 and amended by the Durbin Feeling Languages Act. For this reason, we do not believe it is appropriate to reference specific languages.

We do not believe it is appropriate to revise the definition of ''bilingual or multilingual'' to allow for various levels of proficiency for Native American languages, as we hope to maintain a focus on high levels of proficiency across all languages. At the same time, we appreciate the importance of supporting educators and teacher candidates in reaching proficiency. To meet this need, we added a new priority (Final Priority 2) that allows for pre-service programs that support teacher candidates who are acquiring an additional language but may not yet be highly proficient in the four domains of listening, speaking, reading, and writing. We also revised the definition of ''bilingual or multilingual'' to include languages with fewer than four domains (listening, speaking, reading, and writing), by clarifying that ''bilingual or multilingual'' applies to those with a high level of proficiency in the domains that exist for the language. It is expected that applicants will identify appropriate indicators for measuring proficiency in these languages and equip educators to teach in these languages, and that teacher candidates will finish the pre-service program highly proficient in two or more languages and with a teaching credential.

Additionally, in support of strengthening and revitalizing Native American languages through Native American educators, the Department recently announced [2] new awards totaling more than $11 million for the new Native American Language Resource Centers (NALRC) program, the first-ever Native American Teacher Retention Initiative (NATRI) program, and the State Tribal Education Partnership (STEP) program. Through these awards, the Department seeks to strengthen the vitality of Native American languages in schools, support Native American teachers, and ensure Tribal Educational Agencies can

[1] *https://www.federalregister.gov/citation/85-FR-13640.*

[2] *www.ed.gov/news/press-releases/biden-harris-administration-awards-more-11-million-preserve-native-languages-increase-native-teacher-retention-and-support-tribal-educational-agencies.*

coordinate grant resources alongside State and local partners.

Changes: The Department added new Final Priority 2 and revised the definition of ''bilingual or multilingual'' to include all languages, including those with fewer than four domains.

Priorities

Comment: One commenter suggested that current multilingual educators be offered pathways to other content area certifications. A second commenter recommended opening multilingual teacher training to educators of all content areas, not solely to EL educators.

Discussion: We appreciate the work of bilingual and multilingual teachers and recognize the importance of professional development opportunities to support them in other content areas. The NPD program provides professional development to improve instruction for ELs. This is inclusive of all educators who work with ELs across content areas.

Furthermore, in response to the comment about the availability of training for all teachers of ELs, not just EL educators, we revised Final Priority 4 (formerly Proposed Priority 3) to clarify that current educators of ELs, including content area educators, are eligible for additional development to work in multilingual contexts serving EL students.

Changes: We have revised Final Priority 4 (formerly Proposed Priority 3) to clarify that current educators of ELs, including content area educators, are eligible for additional development to work in multilingual contexts serving EL students.

Comment: Six commenters suggested that the Department support pathways for in-service school leaders to further their knowledge of multilingual learner education. This focus would help to ensure that multilingual teachers have support and guidance from school administration.

Discussion: We agree that school leadership is important in the provision of multilingual education. We added language to Final Priority 4 to clarify that applicants may propose projects to create pathways for school leaders to further their knowledge of multilingual learner education.

Changes: We have added ''school leaders'' to the list of examples of education personnel who may receive in-service professional development under Final Priority 4.

Comment: One commenter recommended that multilingual teacher education programs be encouraged to think strategically about how teachers are prepared to teach content in other languages. Another commenter stated that educators must know English language basics to teach English as a second language in a bilingual classroom. The commenter suggested that professional development should be focused on English language phonics and phonemic awareness for all educators. Finally, a third commenter requested that the Department provide guidance on the types of professional development addressed under these final priorities. The commenter wanted to ensure that the NPD program supports comprehensive training for teachers.

Discussion: We recognize the importance of fully equipping bilingual and multilingual teachers with the knowledge and skills to teach across content areas and languages. The NPD program allows applicants to prepare their pre-service and in-service programs in response to the unique needs of their respective settings, which could include a comprehensive approach or a more targeted focus, such as on a specific content area or on teaching English as a second language in a bilingual classroom.

Changes: None.

Comment: One commenter questioned whether there are enough personnel to guide and oversee newly trained teachers in bilingual education and ensure high-quality teaching.

Discussion: We appreciate the commenter's concern. While this comment referred to oversight on a nationwide scale and cannot be addressed solely through this program, applicants that propose a grant under this program are encouraged to incorporate teacher supervision into their grant proposal to ensure that teachers, in both pre-service and in-service programs, are meeting the expectations of the preparation program.

Changes: None.

Comment: Several commenters commended the efforts to increase opportunities for bilingual education for multilingual learners, stating that increased pre-service opportunities are important and needed. One commenter expressed that there might be confusion created by using the term ''pre-service'' given that, as proposed, this term includes paraprofessionals and those with other teaching credentials who are not currently multilingual teachers. This commenter wanted to ensure that pathways are expanded to diversify the teacher pipeline rather than limited by traditional notions of ''pre-service.'' In addition, two commenters suggested that education and training opportunities be made available to bilingual and multilingual educational assistants working in schools who do not have a college degree or education credentials, and to multilingual, English learner, and emergent bilingual teachers who would like to become credentialed as bilingual educators.

Discussion: While we acknowledge the commenters' concerns, the definition of ''pre-service'' is intended to capture the broad array of pathways to becoming a certified bilingual or multilingual teacher. These pathways can include pre-service programs in which bilingual or multilingual paraprofessionals, who work in schools and are interested in obtaining their teaching credential to support ELs directly, are enrolled. We envision other bilingual and multilingual individuals who are already teachers to be eligible for projects proposed under Final Priority 1 to the extent that they want to move into teaching in bilingual or multilingual education settings. Additionally, we revised Final Priority 4 (formerly Proposed Priority 3) to include individuals who have a teaching credential but have not been teaching in bilingual or multilingual education settings and are pursuing an additional credential to do so.

Changes: We revised Final Priority 4 to include individuals who may have a teaching credential but have not been teaching in bilingual or multilingual education settings and are pursuing an additional credential to do so.

Comment: One commenter expressed support for both Proposed Priority 1 and Proposed Priority 3 (Final Priority 4) as both will help address the teacher shortage for ELs and multilingual learners.

Discussion: The Department appreciates the commenter's support of ELs and their teachers and looks forward to working collectively to address the nationwide teacher shortage of multilingual educators.

Changes: None.

Comment: Eight commenters addressed Proposed Priority 2 (Final Priority 3). Two of these commenters supported the priority because it would create more equitable pathways for aspiring teachers from low-income populations. One of the commenters asked for clarity on how applicants could meet the conditions within Final Priority 3. Another one of these commenters suggested that the Department expand the definition of ''low-income'' to factor in other socioeconomic considerations beyond Pell Grant eligibility. Another of the commenters encouraged the Department to use available data to target programs that serve socioeconomically diverse students. Four of the commenters raised

concerns that Proposed Priority 2 would exclude individuals who are not low-income as defined or do not have the support to apply for Pell grants. Two of the commenters addressed the importance of serving first-generation college applicants as part of Proposed Priority 2.

Discussion: We appreciate the commenters' suggestions. We believe Final Priority 3 will, by design, target programs that are serving socioeconomically diverse students, while allowing for inclusion of students who do not meet the definition of ''low-income.'' Under Final Priority 3 (formerly Proposed Priority 2), 30, 40, or 50 percent of the candidates in a pre-service program must meet the definition of ''low-income.'' This priority imposes a minimum, but outside of this minimum, a project could meet this priority by serving a group of potential candidates that is comprised of 50 to 70 percent of individuals who do not meet the definition of ''low-income.'' Given that the priority would allow for a large percentage of candidates who are not from low-income backgrounds and the importance of building a diverse and representative teacher workforce, we do not believe it is necessary to make changes to the priority.

Finally, we believe that Pell eligibility is a reasonable indicator of low-income status, due to its use as such in other contexts, its validity and reliability, and its availability to institutions. We note that Pell eligibility requirements factor in family size, which is an important consideration in qualifying as low-income. Furthermore, the definition does not require that students have applied for or received Pell Grants, but rather that they would be eligible for, or meet the financial threshold for, a Pell Grant. Accordingly, the definition would not exclude students who lack the support to complete a FAFSA, which is used to determine Pell eligibility. Further, outreach may be conducted as part of an NPD project to help students complete the FAFSA. The purpose of this priority is, in part, to encourage applicants to use funding to work with and recruit students from low-income backgrounds, including those who live in rural areas or who are first-generation candidates, as they transition to and enroll in postsecondary education.

To simplify the definition of ''low-income student,'' we are removing the reference to section 484(a)(5) of the Higher Education Act. This revision does not substantively change the defined term.

Changes: In the definition of ''low-income,'' we have removed the reference to section 484(a)(5) of the Higher Education Act.

Definitions

Comment: Four commenters suggested that the Department explicitly include alternative teacher training pathways in its definition of ''pre-service'' programs rather than only including traditional IHE teacher preparation programs. One of the four commenters recommended that we revise the definition of ''pre-service'' to include individuals who are participating in State-approved programs offered by non-traditional educational providers. Another of the four commenters explained that alternative pathways programs train new teachers more practically, and such pathways may better serve candidates who come from low-income backgrounds, consistent with the focus of Proposed Priority 2 (Final Priority 3).

Discussion: The Department recognizes the value of comprehensive, high-quality alternative pathways programs for preparing new teachers and the importance of responding to the needs of socioeconomically diverse bilingual and multilingual teacher candidates through these programs which can provide more flexibility. We revised the definition of ''pre-service'' to clarify that teacher candidates are not limited to programs solely provided by IHEs; rather they include State-accredited pre-service programs that lead to State-approved full certification or licensure.

Changes: We revised the definition of ''pre-service'' such that it is not limited to teacher education programs only through IHEs.

Final Priorities

The Department establishes the following four priorities for this program. We may use one or more of these priorities in any year in which this program is in effect.

Final Priority 1—Increase the Number of Bilingual or Multilingual Teachers Through a Grow-Your-Own (GYO) Pre-Service Program that Recruits Teacher Candidates who are Bilingual or Multilingual.

Projects that propose to increase the number of fully licensed or certified bilingual or multilingual teachers working in language instruction educational programs or serving ELs, and improve their qualifications and skills, through evidence-based (as defined in 34 CFR 77.1(c)) pre-service programs. Applicants must describe their plan for recruiting, supporting, and retaining teacher candidates who are bilingual or multilingual. Applicants must include in their proposed plan for a pre-service program, one or more of the following GYO strategies that are designed to address shortages of bilingual or multilingual teachers and increase the diversity of qualified individuals entering the educator workforce:

(a) Implementing evidence-based GYO strategies for bilingual or multilingual individuals (*e.g.,* creating dual enrollment, early college, and Career and Technical Education programs in teaching for middle and high school students paired with offering seals of biliteracy or supporting bilingual or multilingual paraprofessionals actively working in P–12 schools in becoming teachers).

(b) Recruiting bilingual or multilingual individuals who may have a teaching credential, but who are not certified to teach bilingual or multilingual education, and supporting them in earning the additional certification.

(c) Implementing evidence-based teacher residencies in bilingual or multilingual education, including scaling these evidence-based pathways through a registered teacher apprenticeship program.

Final Priority 2—Increase the Number of Bilingual or Multilingual Teachers Through a Grow-Your-Own (GYO) Pre-Service Program that Recruits Teacher Candidates who are Emergent Bilinguals or Multilinguals.

Projects that propose to increase the number of fully licensed or certified bilingual or multilingual teachers working in language instruction educational programs or serving ELs, and improve their qualifications and skills, through evidence-based (as defined in 34 CFR 77.1(c)) pre-service programs that recruit teacher candidates who are emergent bilinguals or multilinguals. Applicants must describe their plan for recruiting, supporting, and retaining teacher candidates who are not yet, but are aspiring to be, teachers who are bilingual or multilingual, and their plan for ensuring that teacher candidates complete the pre-service program as fully licensed or certified teachers who are also bilingual or multilingual. Applicants must include in their proposed plan for a pre-service program, one or more of the following GYO strategies that are designed to address shortages of bilingual or multilingual teachers and increase the diversity of qualified individuals entering the educator workforce:

(a) Implementing evidence-based GYO strategies for bilingual or

multilingual individuals (*e.g.,* creating dual enrollment, early college, and Career and Technical Education programs in teaching for middle and high school students paired with offering seals of biliteracy or supporting paraprofessionals actively working in P–12 schools in becoming bilingual or multilingual teachers).

(b) Recruiting individuals who may have a teaching credential, but who are not certified to teach bilingual or multilingual education, and supporting them in earning the additional certification.

(c) Implementing evidence-based teacher residencies in bilingual or multilingual education, including scaling these evidence-based pathways through a registered teacher apprenticeship program.

Final Priority 3—Service to Students from Low-income Backgrounds.

Projects that propose to recruit, prepare, and retain in the pre-service program classes of participants for which one or more of the following conditions are met:

(a) At least 30 percent of the participants are from low-income backgrounds.

(b) At least 40 percent of the participants are low-income students.

(c) At least 50 percent of the participants are low-income students.

Final Priority 4—Improve In-Service Professional Development Programs Targeting Bilingual or Multilingual Educational Personnel Who Serve English Learners.

Projects that propose evidence-based (as defined in 34 CFR 77.1(c)) in-service professional development programs designed to expand the number, and improve the qualifications and skills, of educational personnel working in language instruction educational programs or serving ELs, including—

- Bilingual or multilingual educational paraprofessionals and personnel who are not certified or licensed as teachers;
- Bilingual or multilingual individuals who have a teaching credential but have not been teaching in bilingual or multilingual education settings and are pursuing an additional credential to do so;
- School leaders who are furthering their knowledge and skills to support bilingual or multilingual educators working in language instruction educational programs or serving Els; and
- Other bilingual or multilingual individuals who can benefit from in-service professional development with the goal of increasing the number and skills of individuals working in language instruction educational programs or serving ELs.

Types of Priorities

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

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

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

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

Final Requirements

The Department establishes the following requirements for this program. We may apply one or more of these requirements in any year in which this program is in effect.

Final Application Requirements: An applicant must provide the indicators it proposes to use to determine if a participant meets the definition of ''bilingual or multilingual.'' Applicants may provide this information in response to the selection criteria, or otherwise as applicable, in their applications.

Final Definitions

The Department establishes the following definitions for this program. We may apply one or more of these definitions in any year in which this program is in effect.

Bilingual or multilingual means able to listen, speak, read, and write in two or more languages with at least a high level of proficiency in each language, as determined based on indicators of proficiency established by the grantee. Note, bilingual or multilingual means a high level of proficiency in the domains that exist for the language, which may be fewer than four domains for some languages.

Student from a low-income background means a student—

(a) Who is eligible to receive a Federal Pell Grant for the award year for which the determination is made; or

(b) Who meets the financial threshold to receive a Federal Pell Grant for the year for which the determination is made.

Pre-service means the period of preparation for a person who does not have a teaching certificate or license and who is enrolled in a State-approved teacher education program that leads to a State-approved full certificate or license.

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

Note: This document does *not* solicit applications. In any year in which we choose to use one or more of these priorities, requirements, or definitions, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 14094

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $200 million or more (adjusted every three years by the Administrator of 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;

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

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

(4) Raise legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

This final regulatory action is not a significant regulatory action subject to

review by OMB under section 3(f) of Executive Order 12866, as amended by Executive Order 14094.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866, as amended by Executive Order 14094. To the extent permitted by law, Executive Order 13563 requires that an agency—

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

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

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

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

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

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

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

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

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

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

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

Regulatory Flexibility Act Certification

The Secretary certifies that these final priorities, requirements, and definitions would not have a significant economic impact on a substantial number of small entities.

The small entities that this final regulatory action would affect are IHEs, or public or private entities with relevant experience and capacity, in consortia with LEAs or SEAs applying for and receiving funds under this program. The Secretary believes that the costs imposed on applicants by the final priorities, requirements, and definitions would be limited to paperwork burden related to preparing an application and that the benefits would outweigh any costs incurred by applicants.

Participation in this program is voluntary. For this reason, the final priorities, requirements, and definitions would impose no burden on small entities in general. Eligible applicants would determine whether to apply for funds and can weigh the requirements for preparing applications, and any associated costs, against the likelihood of receiving funding and the requirements for implementing projects under the program. Eligible applicants most likely would apply only if they determine that the likely benefits exceed the costs of preparing an application. The likely benefits include the potential receipt of a grant as well as other benefits that may accrue to an entity through its development of an application, such as the use of that application to seek funding from other sources to address a shortage in bilingual or multilingual teachers working in a language instruction education program or serving ELs.

Paperwork Reduction Act of 1995

These final priorities, requirements, and definitions do not contain any information collection requirements.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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

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

Montserrat Garibay,

Assistant Deputy Secretary and Director for the Office of English Language Acquisition.

[FR Doc. 2024–05202 Filed 3–8–24; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R04–OAR–2022–0741; FRL–10507–02–R4]

South Carolina; Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Control of Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a Clean Air Act (CAA) plan submitted by the South Carolina Department of Health and Environmental Control (SCDHEC) on January 19, 2022. This State plan was submitted to fulfill the requirements of

the CAA and is responsive to EPA's promulgation of Emissions Guidelines (EG) and Compliance Times for municipal solid waste (MSW) landfills. The South Carolina State plan establishes performance standards and other operating requirements for existing MSW landfills and provides for the implementation and enforcement of those standards and requirements.

DATES: This rule is effective on April 11, 2024. The incorporation by reference of certain material listed in the rule is approved by the Director of the Federal Register as of April 11, 2024.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R04–OAR–2022–0741. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Tracy Watson, Regulatory and Community Air Toxics Section, Air Analysis and Support Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth St. SW, Atlanta, Georgia 30303. The telephone number is (404) 562–8998. Mr. Watson can also be reached via electronic mail at *watson.marion@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The EPA published a notice of proposed rulemaking (NPRM) for the State of South Carolina on February 14, 2023 (88 FR 9409). In the NPRM, the EPA proposed the approval of a CAA section 111(d) State plan submitted by the SCDHEC on January 19, 2022. The EPA's analysis of the South Carolina State plan may be found in the aforementioned NPRM and the technical support document (TSD) associated with this docket. Comments on the EPA's proposed approval of the South Carolina State plan for existing MSW landfills were due on or before March 16, 2023. The EPA received no comments during the public comment period.

II. Final Action

The EPA is finalizing approval of South Carolina's section 111(d) State plan for MSW landfills. The State plan was submitted in full compliance with the requirements of 40 CFR part 60, subparts B and Cf. Therefore, EPA is amending 40 CFR part 62, subpart PP to reflect this approval action. This approval is based on the rationale provided in the NPRM and discussed in further detail in the TSD associated with this rulemaking. The EPA's approval is in accordance with the general provisions of plan approval found in 40 CFR part 60, subpart B and 40 CFR part 62, subpart A, and is pursuant to the Agency's role under 42 U.S.C. 7411(d). The EPA's approval of the South Carolina plan is limited to those landfills that meet the criteria established in 40 CFR part 60, subpart Cf, and grants the State authority to implement and enforce the performance standards and source requirements of the EG, except in those cases where authorities are specifically reserved for the EPA Administrator or his designee. Authorities retained by the EPA Administrator are those listed in 40 CFR 60.30f(c).

III. Incorporation by Reference

In accordance with requirements of 1 CFR 51.5, the EPA is finalizing regulatory text that includes incorporation by reference of South Carolina Code Annotated Regulations (S.C. Code Ann. Regs.) 61–62.60, Subpart Cf, which became effective in the State of South Carolina on November 26, 2021. This incorporation establishes emission standards and compliance times for the control of air pollutants from certain MSW landfills that commenced construction, modification, or reconstruction on or before July 17, 2014. S.C. Code Ann. Regs. 61–62.20, Subpart Cf provides details regarding South Carolina's adoption of the applicability provisions, compliance times, emission guidelines, operational standards, test methods, compliance provisions, monitoring requirements, reporting guidelines, recordkeeping guidelines, specifications for active landfill gas collection systems, and definitions contained in EPA's emission guidelines for existing municipal solid waste landfills (40 CFR part 60, subpart Cf). The emissions standards and compliance times established within the South Carolina State plan are at least as stringent as those required by the EG for existing MSW landfills subject to Subpart Cf. The EPA has made, and will continue to make, these materials generally available through the docket for this action, EPA–R04–OAR–2022–0741, at *https://www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). This incorporation by reference has been approved by the Office of the Federal Register as of April 11, 2024, and the plan is federally enforceable under the CAA as of the effective date of this final rulemaking.

IV. Statutory and Executive Order Reviews

In reviewing State plan submissions, EPA's role is to approve State choices, provided they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high

and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

The EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples. EPA performed a screening-level analysis using EPA's EJSCREEN to identify environmental burdens and susceptible populations in communities surrounding MSW landfill facilities in the State. The EJSCREEN did not identify any such communities surrounding the MSW landfill facilities in the State. The results of the demographic analysis are presented in the *EJ Screening Report for Municipal Solid Waste Landfills,* a copy of which is available in the docket for this action, Docket ID No. EPA–R04–EPA–2022–0741.

The EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples because the State plan would reduce emissions of landfill gas, which contains both nonmethane organic compounds and methane. Nonmethane organic compounds can contain various organic hazardous air pollutants (HAPs) and volatile organic compounds (VOCs). Nearly 30 organic HAPs have been identified in uncontrolled landfill gas, with at least one identified as a known human carcinogen. VOC emissions are precursors to particulate matter and ozone formation, both of which are associated with health effects such as premature mortality for adults and infants, cardiovascular morbidity such as heart attacks, and respiratory morbidity such as asthma attacks, acute bronchitis, and other respiratory symptoms. Additionally, the State plan is expected to result in a reduction of carbon dioxide due to reduced demand by landfills for electricity from the grid, as landfills will generate electricity from landfill gas. These abated emissions will improve air quality and reduce the effects associated with exposure to landfill gas emissions, protecting public health and welfare. The EPA has determined that this action increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or income or environmental effects on any population, including any minority, low-income, or indigenous populations. To the extent that any minority, low-income, or indigenous subpopulation is disproportionately impacted by landfill gas emissions due to the proximity of their homes to sources of these emissions, that subpopulation also stands to see increased environmental and health benefit from the emission reductions called for by this action.

In addition, this proposed approval of South Carolina's State plan for existing MSW landfills does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the State plan is not approved to apply in Indian country located in the State, and the EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 13, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Landfills, Methane, Ozone, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Date: March 1, 2024.

Jeaneanne Gettle,

Acting Regional Administrator Region 4.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 62 as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

■ 2. Revise § 62.10160 and the undesignated center heading above it to read as follows:

Emissions From Existing Municipal Solid Waste Landfills—Section 111(d) Plan

§ 62.10160 Identification of sources.

(a) *Identification of plan.* South Carolina's State Plan for Existing Municipal Solid Waste Landfills, as submitted on January 19, 2022. The plan includes the regulatory provisions cited in paragraph (d) of this section, which EPA incorporates by reference.

(b) *Identification of sources.* The plan applies to each existing municipal solid waste landfill in the State of South Carolina that commenced construction on or before July 17, 2014, as such landfills are defined in 40 CFR 60.41f and 40 CFR part 60.

(c) *Effective date.* The effective date of the plan is April 11, 2024.

(d) *Incorporation by reference.* Material listed in this paragraph (d) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact EPA at: EPA Region 4 office, 61 Forsyth St. SW, Atlanta, Georgia 30303, 404–562–9900. 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.* The material may be obtained from the State of South Carolina—The Legislative Council of the General Assembly, Office of the State Register, Fourth Floor, Rembert C. Dennis Building, 1000 Assembly Street, Columbia, SC 29201; phone: (803) 212–4500; email: *REG@scstatehouse.gov;* website: *https://www.scstatehouse.gov.*

(1) S.C. Code Ann. Regs. 61–62.60, Subpart Cf. South Carolina Code Annotated Regulations, Chapter 61—Department of Health and

Environmental Control, 61–62—Air Pollution Control Regulations and Standards, 61–62.60—South Carolina Designated Facility Plan and New Source Performance Standards, subpart Cf—Performance Standards and Compliance Times for Existing Solid Waste Landfills, effective November 26, 2021.

(2) [Reserved]

[FR Doc. 2024–04942 Filed 3–11–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 21–402, 02–278, 17–59; FCC 23–107; FR ID 207543]

Targeting and Eliminating Unlawful Text Messages, Implementation of the Telephone Consumer Protection Act of 1991, Advanced Methods To Target and Eliminate Unlawful Robocalls; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: On January 2, 2024, the Federal Communications Commission (Commission) published a final rule requiring terminating mobile wireless providers to block text messages from a particular number following notification from the Commission. The Commission also codified that the National Do-Not-Call (DNC) Registry's protections extend to text messages. An amendment in the final rule with a delayed effective date provided an incomplete revision of a certain paragraph. This document corrects that amendatory instruction.

DATES: This correction is effective January 27, 2025.

FOR FURTHER INFORMATION CONTACT: Jerusha Burnett of the Consumer Policy Division, Consumer and Governmental Affairs Bureau, at *jerusha.burnett@fcc.gov,* 202 418–0526, or Mika Savir of the Consumer Policy Division, Consumer and Governmental Affairs Bureau, at *mika.savir@fcc.gov* or (202) 418–0384.

SUPPLEMENTARY INFORMATION: In the final rule published January 26, 2024, the Commission amended 47 CFR 64.1200. One of the amendments revises paragraph (f)(9)(i), effective January 27, 2025. However, the instruction for the revision incorrectly stated the entire paragraph (f)(9) is revised, which would result in the loss of paragraph (f)(9)(ii), as it was not provided in the revised text. The Commission did not intend to remove paragraph (f)(9)(ii), and this correction lists the specific revision to paragraph (f)(9).

Correction

In FR Rule Doc. No. 2023–28832 appearing on page 5098 in the **Federal Register** of Friday, January 26, 2024, the following correction is made:

§ 64.1200 [Corrected]

■ 1. On page 5105, in the first column, in amendment 6, the instruction ''Effective January 27, 2025, further amend § 64.1200 by revising paragraph (f)(9) to read as follows:'' is corrected to read ''Effective January 27, 2025, further amend § 64.1200 by revising paragraphs (f)(9) introductory text and (f)(9)(i) to read as follows:''.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–05241 Filed 3–11–24; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 89, No. 49
Tuesday, March 12, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–0485; Airspace Docket No. 23–ASW–16]

RIN 2120–AA66

Amendment of Jet Route J–183, United States Area Navigation (RNAV) Routes Q–4 and T–254, and Very High Frequency Omnidirectional Range (VOR) Federal Airways V–76, V–161, V–565, and V–568; Establishment of RNAV Route T–499; and Revocation of VOR Federal Airway V–558 in the Vicinity of Llano, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Route J–183, United States Area Navigation (RNAV) Routes Q–4 and T–254, and Very High Frequency Omnidirectional Range (VOR) Federal Airways V–76, V–161, V–565, and V–568; establish RNAV Route T–499; and revoke VOR Federal Airway V–558. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Llano, TX (LLO), VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). The Llano VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before April 26, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–0485 and Airspace Docket No. 23–ASW–16 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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

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 would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal

business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Jet routes are published in paragraph 2004, RNAV routes (Q-routes) are published in paragraph 2006, VOR Federal airways are published in paragraph 6010(a), and RNAV routes (T-routes) are published in paragraph 6011 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 proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

Background

The FAA is planning to decommission the VOR portion of the Llano, TX, VORTAC in October 2024. The Llano VOR is one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** on July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Llano VORTAC is planned for decommissioning, the co-located Tactical Air Navigation (TACAN) portion of the NAVAID is being retained. The TACAN would continue to provide navigational service for military operations and Distance Measuring Equipment (DME) service supporting current and future NextGen PBN flight procedure requirements.

The Air Traffic Service (ATS) routes affected by the planned decommissioning of the Llano VOR are J–183, V–76, V–161, V–558, V–565, and V–568. With the planned decommissioning of the Llano VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected routes. As such, proposed modifications to J–183, V–76 and V–565 would result in the ATS routes being shortened; to V–161 would result in a third gap being added; to V–568 would result in the existing gap being expanded; and to V–558 would result in the airway being revoked.

To address the proposed amendments to the affected ATS routes, instrument flight rules (IFR) traffic could use J–86 in the high-altitude stratum or use V–66, V–68, V–77, and V–306 in the low-altitude stratum to navigate around the area affected by the planned decommissioning of the Llano VOR. Additionally, IFR pilots equipped with RNAV capabilities could also navigate using Q–4 (once amended), T–254 (once amended), T–466, and T–499 (proposed to be established) or point-to-point using the existing Fixes and waypoints (WP) that would remain in place to support continued operations though the affected area. Visual flight rules pilots who elect to navigate via the affected ATS routes could also take advantage of the adjacent conventional airways listed above, as well as the listed RNAV routes and point-to-point navigation, if properly equipped. Lastly, all aircraft have the option to request and receive radar vectors from air traffic control (ATC) to transit the affected area as well.

With the planned decommissioning of the Llano VOR, the FAA also plans to extend RNAV Routes Q–4 and T–254, and to establish RNAV Route T–499. The Q–4 and T–254 route extensions would mitigate the proposed amendments to J–183 between the Pecos, TX, VOR/Distance Measuring Equipment (VOR/DME) and the College Station, TX, VORTAC and to V–76 between the San Angelo, TX, VORTAC and the DILLO, TX, WP (located in the immediate vicinity of the Llano, TX, VORTAC). The new RNAV Route T–499 would mitigate the amendment to V–568 between the Corpus Christi, TX, VORTAC and the DILLO WP.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend Jet Route J–183, RNAV Routes Q–4 and T–254, and VOR Federal Airways V–76, V–161, V–565, and V–568; establish RNAV Route T–499; and revoke VOR Federal Airway V–558. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Llano, TX, VORTAC. The proposed ATS route actions are described below.

J–183: J–183 currently extends between the El Paso, TX, VORTAC and the College Station, TX, VORTAC. The FAA proposes to remove the route segment between the Pecos, TX, VOR/DME and the College Station VORTAC. As amended, the route would be changed to extend between the El Paso VORTAC and the Pecos VOR/DME.

Q–4: Q–4 currently extends between the BOILE, CA, Fix and the El Paso, TX, VORTAC. The FAA proposes to extend the route eastward from the El Paso VORTAC to the College Station, TX, VORTAC to mitigate the proposed removal of the J–183 route segment addressed above. In addition, the FAA proposes to remove the ZEBOL, AZ, WP from the route description because it does not denote a route turn point of one degree or more and there is no published holding at the WP. However, the ZEBOL WP will continue to be depicted on the IFR En Route charts because it is used for ATC purposes. Lastly, the FAA proposes to make minor editorial corrections to the route description to list the state in which each route point is located, spell out the names of the navigational aids, and update the geographic coordinates of each route point to be expressed in degrees, minutes, seconds, and hundredths of a second. As amended, the route would be changed to extend between the BOILE Fix and the College Station VORTAC. The full Q–4 route description is listed in the regulatory text of this notice of proposed rulemaking.

V–76: V–76 currently extends between the Lubbock, TX, VORTAC and the Industry, TX, VORTAC. The FAA proposes to remove the airway segment between the San Angelo, TX, VORTAC and the Industry VORTAC. As amended, the airway would be changed to extend between the Lubbock VORTAC and the San Angelo VORTAC.

V–161: V–161 currently extends 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/DME and the Winnipeg, Manitoba (MB), Canada VORTAC, excluding the airspace within Canada. The FAA proposes to remove the airway segment between the Center Point, TX, VORTAC and the Millsap, TX, VORTAC. As amended, the airway would be changed to extend between the Three Rivers VORTAC and the Center Point VORTAC; between the Millsap VORTAC and the Tulsa VORTAC; between the Butler VORTAC and the Gopher VORTAC; and between the International Falls VOR/DME and the Winnipeg, MB, Canada VORTAC, excluding the airspace within Canada. Additional amendments to the airway have been proposed in a separate rulemaking action.

V–558: V–558 currently extends between the Llano, TX, VORTAC and the Industry, TX, VORTAC. The FAA

proposes to remove the airway in its entirety.

V–565: V–565 currently extends between the Llano, TX, VORTAC and the Lufkin, TX, VORTAC. The FAA proposes to remove the airway segment between the Llano VORTAC and the Centex, TX, VORTAC. As amended, the airway would be changed to extend between the Centex VORTAC and the Lufkin VORTAC.

V–568: V–568 currently extends between the Corpus Christi, TX, VORTAC and the Llano, TX, VORTAC; and between the Millsap, TX, VORTAC and the Wichita Falls, TX, VORTAC. The FAA proposes to remove the airway segment between the Stonewall, TX, VORTAC and the Llano VORTAC. As amended, the airway would be changed to extend between the Corpus Christi VORTAC and the Stonewall VORTAC and between the Millsap VORTAC and the Wichita Falls VORTAC.

T–254: T–254 currently extends between the College Station, TX, VORTAC and the Lake Charles, LA, VORTAC. The FAA proposes to extend the route westward from the College Station VORTAC to the San Angelo, TX, VORTAC to mitigate a portion of the proposed V–76 airway segment removal between the San Angelo VORTAC and the Llano, TX, VORTAC. The route extension would include the DILLO, TX, WP; the KALLA, TX, Fix; and the DOWWD, TX, WP (being established). Additionally, the FAA proposes to replace the Lake Charles VORTAC route point with the KNZLY, LA, WP being established in the immediate vicinity of the Lake Charles VORTAC. Lastly, the FAA proposes to make minor editorial corrections to the route description to update the geographic coordinates of each route point to be expressed in degrees, minutes, seconds, and hundredths of a second. As amended, T–254 would extend between the San Angelo VORTAC and the KNZLY WP. The full T–254 route description is listed in the regulatory text of the notice of proposed rulemaking.

T–499: T–499 is a new RNAV route the FAA proposes to establish between the Corpus Christi, TX, VORTAC and the DILLO, TX, WP. This new T-route would provide RNAV routing between the Corpus Christi, TX, area and the Llano, TX, area to mitigate the proposed removal of the V–568 airway segment addressed above. The full T–499 route description is listed in the regulatory text of the notice of proposed rulemaking.

All NAVAID radials listed in the VOR Federal airway descriptions in the regulatory text of this notice of proposed rulemaking are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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 proposed 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

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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–183 [Amended]

From El Paso, TX; to Pecos, TX.

* * * * *

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–4 BOILE, CA TO COLLEGE STATION, TX (CLL) [AMENDED]

BOILE, CA	FIX	(Lat. 34°25′20.78″ N, long. 118°01′33.07″ W).
HEDVI, AZ	WP	(Lat. 33°32′23.00″ N, long. 114°28′14.00″ W).
SCOLE, AZ	FIX	(Lat. 33°27′45.80″ N, long. 114°04′54.40″ W).
SPTFR, AZ	WP	(Lat. 33°23′49.00″ N, long. 113°43′29.00″ W).
SKTTR, AZ	WP	(Lat. 32°17′38.00″ N, long. 109°50′44.00″ W).
El Paso, TX (ELP)	VORTAC	(Lat. 31°48′57.28″ N, long. 106°16′54.78″ W).
Pecos, TX (PEQ)	VOR/DME	(Lat. 31°28′09.53″ N, long. 103°34′29.12″ W).
DILLO, TX	WP	(Lat. 30°47′46.76″ N, long. 098°47′13.91″ W).
College Station, TX (CLL)	VORTAC	(Lat. 30°36′18.01″ N, long. 096°25′14.45″ W).

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–76 [Amended]

From Lubbock, TX; INT Lubbock 188° and Big Spring, TX, 286° radials; Big Spring; to San Angelo, TX. From Centex, TX; to Industry, TX.

* * * * *

V–161 [Amended]

From Three Rivers, TX; to Center Point, TX. From Millsap, TX; 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. From International Falls, MN; to Winnipeg, MB, Canada, excluding the airspace within Canada.

* * * * *

V–558 [Removed]

* * * * *

V–565 [Amended]

From Centex, TX; College Station, TX; to Lufkin, TX.

* * * * *

V–568 [Amended]

From Corpus Christi, TX; INT Corpus Christi 296° and Three Rivers, TX, 165° radials; Three Rivers; INT Three Rivers 327° and San Antonio, TX, 183° radials; San Antonio; to Stonewall, TX. From Millsap, TX; to Wichita Falls, TX.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–254 SAN ANGELO, TX (SJT) TO KNZLY, LA [AMENDED]

San Angelo, TX (SJT)	VORTAC	(Lat. 31°22′29.84″ N, long. 100°27′17.53″ W).
DILLO, TX	WP	(Lat. 30°47′46.76″ N, long. 098°47′13.91″ W).
KALLA, TX	FIX	(Lat. 30°43′15.88″ N, long. 098°04′38.46″ W).
DOWWD, TX	WP	(Lat. 30°44′58.33″ N, long. 097°06′12.22″ W).
College Station, TX (CLL)	VORTAC	(Lat. 30°36′18.01″ N, long. 096°25′14.45″ W).
EAKES, TX	WP	(Lat. 30°33′18.00″ N, long. 095°18′29.00″ W).
CREPO, TX	WP	(Lat. 30°16′54.00″ N, long. 094°14′43.00″ W).
KNZLY, LA	WP	(Lat. 30°08′29.48″ N, long. 093°06′19.37″ W).

* * * * *

T–499 CORPUS CHRISTI, TX (CRP) TO DILLO, TX [NEW]

Corpus Christi, TX (CRP)	VORTAC	(Lat. 27°54′13.56″ N, long. 097°26′41.57″ W).
CARTI, TX	FIX	(Lat. 28°09′46.08″ N, long. 098°02′51.29″ W).
LEMIG, TX	FIX	(Lat. 28°58′37.91″ N, long. 098°30′03.52″ W).
San Antonio, TX (SAT)	VORTAC	(Lat. 29°38′38.51″ N, long. 098°27′40.74″ W).
Stonewall, TX (STV)	VORTAC	(Lat. 30°12′24.33″ N, long. 098°42′20.72″ W).
DILLO, TX	WP	(Lat. 30°47′46.76″ N, long. 098°47′13.91″ W).

* * * * *

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

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–05180 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 382

[Docket No. DOT–OST–2022–0144]

RIN 2105–AF14

Ensuring Safe Accommodations for Air Travelers With Disabilities Using Wheelchairs

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT or the Department).

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: The U.S. Department of Transportation (DOT or the Department) is proposing to strengthen its rule implementing the Air Carrier Access Act (ACAA) to address the serious problems that individuals with disabilities using wheelchairs and scooters face when traveling by air that impact their safety and dignity, including mishandled wheelchairs and scooters and improper transfers to and from aircraft seats, aisle chairs, and personal wheelchairs.

DATES: Comments should be filed by May 13, 2024. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2022–0144 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, Washington, DC between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2022–0144 or the Regulatory Identification Number (RIN 2105–AF14) for the rulemaking at the beginning of your comment. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone can search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents and comments received, go to *https://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Christopher Miller, Staff Attorney, or Blane Workie, Assistant General Counsel, of the Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *christopher.miller1@dot.gov* or *blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

The Department is issuing this notice of proposed rulemaking (NPRM) to increase access to safe and dignified air travel for individuals with disabilities. Air travel connects individuals to family and friends, jobs, and vital services, and it opens the door to opportunity. However, air travel can be especially difficult for individuals who use wheelchairs or scooters and rely on disability-related physical assistance and services provided by U.S. or foreign air carriers [1] (''carriers'' or ''airlines'')

[1] ''Carrier'' is defined as ''a U.S. citizen (''U.S. carrier'') or foreign citizen (''foreign carrier'') that undertakes, directly or indirectly, or by a lease or

and their contractors. Damaged and delayed personal wheelchairs and assistive devices and untimely and unsafe assistance provided by airlines can lead to serious life disruptions such as loss of mobility independence, personal injury, lost opportunities and wages, and other significant harms. Some wheelchair users even avoid flying altogether because of these risks.

B. Statutory Authority

The Air Carrier Access Act, 49 U.S.C. 41705, prohibits discrimination in airline service because of disability by U.S. and foreign air carriers. When it enacted the ACAA, Congress directed the Department ''to promulgate regulations to ensure non-discriminatory treatment of qualified handicapped individuals consistent with safe carriage of all passengers on air carriers.'' Public Law 99–435, 3, 100 Stat. 1080, 1080 (1986). The Department responded by issuing a final rule that required carriers to provide nondiscriminatory service to individuals with disabilities. 55 FR 8008 (Mar. 6, 1990). The Department has continually updated these regulations pursuant to the ACAA and with its rulemaking authority under 49 U.S.C. 40113, which states that the Department may take action that it considers necessary to carry out its statutory duties, including prescribing regulations.

To the extent that violations of the ACAA and part 382 result in injuries to passengers with disabilities and occur in interstate air transportation, the incidents are also violations of 49 U.S.C. 41702, which require air carriers to provide safe and adequate interstate air transportation. It is well-established that section 41702 may be used to ensure ''safe and adequate'' service in a civil rights context.[2]

Furthermore, section 440 of the FAA Reauthorization Act of 2018 (2018 FAA Act) directs the Department to review, and if necessary revise, applicable regulations to ensure that passengers with disabilities receive dignified, timely, and effective assistance at airports and onboard aircraft from trained personnel and to ensure that airline personnel who provide physical assistance to passengers with disabilities receive annual training that includes, as appropriate, hands-on instructions and the appropriate use of relevant equipment.

C. Summary of Regulatory Provisions

TABLE 1—SUMMARY OF NPRM PROPOSALS

Subject	Proposal
Safe and Dignified Assistance	Clarifies that safe and dignified assistance to individuals with disabilities is required when providing required accommodations.
Prompt Enplaning, Deplaning, and Connecting Assistance.	Clarifies that prompt enplaning, deplaning, and connecting assistance is required, including moving within the airport terminal. Prompt is determined based on the totality of circumstances, except when physical assistance is needed to disembark the aircraft, in which case prompt means that: (1) personnel and boarding wheelchair must be available to deplane the passenger when the last passenger who did not request deplaning assistance departs the aircraft; and (2) the passenger's personal wheelchair must be available as close as possible to the door of the aircraft to the maximum extent possible, except: (a) where this practice would be inconsistent with Federal regulations governing transportation security or the transportation of hazardous materials, (b) or when the passenger requests the wheelchair be returned at a location other than the door of the aircraft. If the passenger requests the wheelchair be returned at a location other than the door of the aircraft, an airport wheelchair must be available for the passenger's use.
Mishandling of Wheelchairs and Assistive Devices as Per Se Violation.	Defines *mishandled* to mean lost, delayed, damaged, or pilfered (*i.e.,* stolen). Specifies that any mishandling of wheelchairs and assistive devices by airlines is a per se regulatory violation subject to administrative penalties. In the event of any mishandling of a wheelchair or scooter, requires airlines to immediately notify impacted passengers of their rights: (1) to file a claim with the airline, (2) to receive a loaner wheelchair from the airline with certain customizations, (3) to choose a preferred vendor, if desired, for device repairs or replacement, and (4) to have a Complaints Resolution Official (CRO) available and be provided information on how to contact the CRO.
Passenger Notifications After Wheelchair Is Loaded on and Unloaded from Aircraft.	Requires airlines to timely notify passengers when their wheelchairs or scooters have been loaded to and unloaded from the cargo compartment of their flights. Requires airlines to notify passengers immediately upon learning that the passenger's wheelchair or scooter does not fit on the plane.
Prompt Return of Delayed Wheelchairs or Scooters.	Requires airlines to transport a delayed wheelchair or scooter to the passenger's final destination within 24 hours of the passenger's arrival by whatever means possible. Requires airlines to provide the passenger a choice between picking up the wheelchair or scooter at his or her destination airport or having the wheelchair delivered to another location based on a reasonable request by the passenger, such as the passenger's home or hotel. Depending on the passenger's choice, the Department would consider the wheelchair or scooter to be provided to the passenger (1) when the wheelchair or scooter is transported to a location requested by the passenger if the passenger chooses to have it delivered, regardless of whether the passenger is present to take possession of the wheelchair or scooter; or (2) when the wheelchair or scooter has arrived at the destination airport, is available for pickup, and the carrier has provided notice to the passenger of the location and availability of the wheelchair or scooter for pickup if the passenger chooses to pick it up.
Prompt Repair or Replacement of Damaged Wheelchairs or Scooters.	Following a mishandling, requires airlines to provide passengers the option of: (1) the carrier handling the repair or replacement of the device , with a device of equivalent or greater function and safety, within a reasonable timeframe and paying the associated costs; or (2) the passenger arranging for the repair or replacement of the device, with a device of equivalent or greater function and safety, through his or her preferred vendor with the carrier having the responsibility to transport the device to the preferred vendor and pay the vendor directly for the repairs or replacement.

any other arrangement, to engage in air transportation.'' 14 CFR 382.3.

[2] *See* Frontier Airlines, Inc., Order 2017–7–8 (July 21, 2017); United Airlines, Inc., Order 2016–1–3 (January 15, 2016); U.S. Airways, Inc., Order 2003–3–19 (March 26, 2003); American Airlines, Inc., Order 2003–3–1 (March 4, 2003).

TABLE 1—SUMMARY OF NPRM PROPOSALS—Continued

Subject	Proposal
Loaner Wheelchair Accommodations ..	Requires airlines to provide loaner wheelchairs while individuals with disabilities are waiting on repairs or replacement of a mishandled device. Requires airlines to consult with the individual receiving the loaner wheelchair to ensure that the loaner wheelchair fits the passenger's functional needs, as much as possible, and safety-related needs.
Enhanced Training for Certain Airline Personnel and Contractors.	Requires annual training, including hands-on training, of airline employees and contractors who physically assist passengers with mobility disabilities or handle passengers' wheelchairs or scooters.
New Improved Standards for On-Board Wheelchairs (OBW).	Requires new improved performance standards for OBWs on twin-aisle aircraft and aircraft with 60 or more seats, consistent with standards for OBWs on single-aisle aircraft with 125 or more seats.
Size Standard for Lavatories on Twin-Aisle Aircraft.	Seeks comments regarding whether to specify that one lavatory needs to be of sufficient size: (1) to permit both a passenger with a disability and an attendant to enter and maneuver within the lavatory; and (2) to set a 95th percentile male standard for the individual with a disability and the attendant in place of the non-specific standard currently set forth for twin-aisle aircraft lavatories.
Reimbursement of Fare Difference	Seeks comments regarding whether U.S. and foreign air carriers should be required to reimburse the difference between the fare on a flight a wheelchair user took and the fare on a flight that the wheelchair or scooter user would have taken if his or her wheelchair or scooter had been able to fit in the cabin or cargo compartment of the aircraft.

D. Summary of Preliminary Regulatory Analysis

TABLE 2—SUMMARY OF ANNUALIZED MONETIZED COSTS AND MONETIZED BENEFITS, DISCOUNTED AT 7 PERCENT

Subject	Costs	Benefits
Safe, Dignified, and Prompt Assistance	$0	$0
Mishandling of Wheelchairs and Assistive Devices as Per Se Violation	$0	$0
Passenger Notifications; Return, Repair, and Replacement of Wheelchairs and Scooters; and Loaner Wheelchair Accommodations.	$0	$0
Enhanced Training for Certain Airline Personnel and Contractors	$5.44 million	$6.0 million
New Improved Standards for On-Board Wheelchairs (OBWs)	$700,000	$0
Total	$6.1 million	$6.0. million

The quantifiable benefits of this rulemaking included in the current analysis are anticipated to be slightly less than the quantifiable costs. However, we note that the quantified benefits are underestimated because certain benefits are not included. The Department believes the benefits of the proposed rule would exceed and justify the costs if the unquantified benefits were included.

The proposed rule and training requirements are expected to have unquantified benefits of reduced injuries, including fatalities, sustained by individuals with disabilities while receiving physical assistance from airline staff and contractors and after wheelchair and scooter mishandlings. Other types of injuries, including injuries to airline personnel and contractors, were also not quantified due to data limitations. The wheelchair handling training provision is expected to reduce repair costs due to avoided wheelchair mishandlings. This benefit has been quantified in the analysis. Additional unquantified benefits of this rulemaking include improved dignity, improved mobility by reduced mishandlings and improved loaner wheelchair accommodations, reduced wait times for mishandled wheelchairs to be returned to passengers, and improved lavatory accessibility. Also, the Department believes that this rulemaking could help restore confidence in flying for many individuals with disabilities, which in turn would yield great benefits for individuals with disabilities and industry stakeholders. Additional information and questions for comment can be found in the docket in the full-length regulatory impact analysis (RIA).

II. Need for a Rulemaking

A. Concerns Raised to DOT

Disability rights advocates have raised concerns to the Department regarding unsafe, inadequate, and undignified assistance that individuals with mobility impairments receive from airlines when flying. These concerns have primarily focused on delayed and damaged personal wheelchairs or scooters, unsafe transfers to and from wheelchairs and aircraft seats, and lack of prompt wheelchair assistance at the airport.

These advocates have emphasized that many passengers with disabilities have received bumps and bruises and, in other cases, far more significant injuries like broken bones, dislocated joints, and open wounds during the boarding and deplaning process. As evidence, one disability organization specifically recounted several recent incidents where its members had experienced significant difficulties during the boarding and deplaning process. These included a failed transfer resulting in a fractured tailbone and subsequent infection; being hand-carried off an airplane; and improper use of an aisle chair. An aisle chair is a wheelchair that is used in the enplaning and deplaning process to transport an individual with a mobility disability between their own wheelchair, or an airport wheelchair, and an aircraft seat. Improper use of aisle chairs can result in passengers bumping into armrests while being transported to their seats and improper transfers can result in passengers being dropped when moving from aisle chairs to their seats.[3] Because transfers to and

[3] Additional related information can be found in Paralyzed Veterans of America's (PVA) Rulemaking Petition, viewable in the rulemaking's docket, Docket DOT–OST–2022–0144, and available online at *https://www.regulations.gov/docket/DOT-OST-2022-0144*. PVA has separately submitted a formal

from aircraft seats and wheelchairs are the most physically intensive type of assistance provided by airline personnel and contractors and can cause serious bodily harm to passengers and workers if not done properly, the advocates—representing both passengers with disabilities and workers—have urged the Department to require enhanced training in this area.

The advocates have also maintained that damage to passengers' personal wheelchairs and scooters can result from insufficient training.[4] Wheelchair users today cannot travel in their own wheelchairs and must surrender their wheelchairs to an airline for stowage prior to travel. This means passengers must rely on airline staff and contractors to properly handle a wheelchair or scooter and return it in the condition it was received. The advocates have stressed to the Department that, when an individual's wheelchair or scooter is delayed or damaged by an airline, the individual's mobility, health, and freedom are impacted until the device can be returned, repaired, or replaced. According to advocates, wheelchairs are custom-fitted to meet the needs and shape of each user. Spending time in an ill-fitting chair can cause serious injury, such as pressure sores, and even death as a result of a subsequent infection. Further, loaner devices may lack the customized assistive technology that helps the individual speak or breathe, and have inadequate functions that limit mobility. A disability organization also asserted that, according to its survey, the top reason individuals with mobility impairments avoid travel is because of concerns about wheelchair damage.[5]

The concerns of the disability community were further echoed by the hundreds of people who participated in the Department's Public Meeting on Air Travel by Persons Who Use Wheelchairs, which was held virtually on March 24, 2022, and the many others who submitted written comments to the meeting's docket.[6] The purpose of the meeting was to listen and learn from individuals who use wheelchairs on the difficulties that they encounter during air travel and from airlines on both the challenges that they face in providing accessible air transportation and the actions that they are taking, or plan to take, to improve the air travel environment for wheelchair users. The Department heard from many individuals with disabilities about how a mishandled wheelchair is a significant and serious problem that endangers their health and limits their mobility and independence. For example, one commenter stated, ''These are not one-size-fits-all products and damaging them can have enormous negative consequences for the person having to use them. Recreating damaged or lost chairs takes time and money.'' [7] Another individual wrote, ''My [wheelchair] has come back to me with missing pieces and scratches and scrapes. Think of a wheelchair as essentially being my legs and when my 'legs' are damaged or broken then I cannot go about my daily activities.'' [8]

Individuals with disabilities also shared their perspectives on the negative effects of significant delays in receiving wheelchair assistance, actions that they believe airlines should take when a wheelchair has been mishandled, and the harm that they suffer because of unsafe transfers to and from aircraft seats, aisle chairs, or their personal wheelchairs. A disability organization stated that ''[w]ait times [for assistance] can be astronomical,'' resulting in significant consequences including wasted time, missed connections, and additional time spent without access to the restroom, which can have significant health impacts for individuals.[9] Regarding transfers, another individual wrote that ''[t]he process of transferring out of our wheelchairs can be inconvenient at best and traumatizing at worst,'' and recommended that ''[t]he Department of Transportation must hold airlines accountable for the injuries that they cause people with disabilities.'' [10]

In association with the March 2022 meeting, the Department received approximately 192 written comments from advocates, airlines, other industry stakeholders, and individuals in response to the public meeting. Generally, comments discussed mishandled wheelchairs (including damages and delays, related airline procedures for handling, assistance after a mishandling, and related training for airline personnel), safety of physical assistance (including transfers, use of equipment such as aisle chairs, and related training for airline personnel), or other miscellaneous topics.

Individuals and advocates also described several potential actions to address these issues. Some ideas they raised included:

- Holding airlines accountable and enforcing higher penalties against airlines for wheelchair damages;
- Enhancing the designs of aisle chairs, wheelchairs, and aircraft cargo compartments;
- Requiring airlines to use certain equipment and establish processes for handling wheelchairs and physically assisting passengers with mobility impairments;
- Requiring airlines to provide additional training, including hands-on training, to employees and contractors; and
- Allowing passengers to use their personal wheelchairs on-board aircraft.[11]

Representatives of airlines noted that the industry is currently making best efforts to accommodate passengers with disabilities and to mitigate any negative consequences, including by providing appropriate training to personnel, starting repair and replacement procedures immediately after mishandlings, and working directly with passengers to secure loaner wheelchairs that best meet passengers' needs. Some airlines also advocated for other key stakeholders (*e.g.,* airports, mobility aid service providers, mobility aid manufacturers, airport vendors, and travel agents) to assist in addressing problems outside of their control. Further, airline representatives believe that any new training requirements must be adaptable and that recurrent hands-on training should be limited to employees who are involved in a mishandling incident or have failed to follow procedures, due to training cost considerations.

complaint to the Department detailing many other similar travel experiences of its members from 2022. The formal complaint's docket number is DOT–OST–2022–0075.

[4] *See,* PVA's Rulemaking Petition, Docket DOT–OST–2022–0144, and available online at *https://www.regulations.gov/docket/DOT-OST-2022-0144.*

[5] PVA's informal online survey, titled *The ACAA Survey,* and its results were published in September 2022 and can be accessed online at *https://pva.org/wp-content/uploads/2022/09/2022-ACAA-Survey-Results-FINAL.pdf.*

[6] *See* Docket DOT–OST–2022–0014, available online at *https://www.regulations.gov/docket/DOT-OST-2022-0014.*

[7] *See* Comment from Robert Westal, posted to the meeting's docket on April 18, 2022, available online at *https://www.regulations.gov/comment/DOT-OST-2022-0014-0172.*

[8] *See* Comment from Kelly Pelong, posted to the meeting's docket on April 22, 2022, available online at *https://www.regulations.gov/comment/DOT-OST-2022-0014-0178.*

[9] *See* Comment from National Council on Independent Living, posted to the meeting's docket on April 8, 2022, available online at *https://www.regulations.gov/comment/DOT-OST-2022-0014-0141.*

[10] *See* Comment from Stephanie Woodward, posted to the meeting's docket on April 25, 2022, available online at *https://www.regulations.gov/comment/DOT-OST-2022-0014-0186.*

[11] In FY2023, the Federal Aviation Administration (FAA) initiated a three-year research roadmap to investigate the feasibility of enabling passengers to stay in their personal wheelchairs while travelling on commercial aircraft. This research program builds on the U.S. Access Board and Transportation Research Board Report on the *Feasibility of Wheelchair Securement Systems on Passenger Aircraft* and may support potential future rulemaking.

B. Disability-Related Complaint Data and Mishandled Wheelchair Data

Disability complaints filed with the Department and the airlines demonstrate dissatisfaction with the assistance provided to wheelchair users during air travel. Further, the mishandled wheelchair and scooter data that the Department requires airlines to report monthly shows that the number of mishandled wheelchairs and scooters is just as high today as it was in calendar year 2019, when airlines first reported this data for the full year. It also reveals that the wheelchairs and scooters are mishandled at a much higher rate than checked bags.[12]

Inadequate wheelchair assistance, which includes untimely assistance and unsafe physical assistance, is the top disability complaint category for the Department and airlines. These complaints account for more than 40% of all disability-related complaints that consumers filed with the Department from 2013 to 2022.[13] Also, more than 46% of the disability-related complaints that U.S. and foreign air carriers received directly from consumers from 2013 to 2021 were related to inadequate wheelchair assistance.[14] In addition, from 2013 to 2022, the number of complaints regarding inadequate wheelchair assistance that the Department received from consumers and that the airlines received directly from consumers increased significantly.[15]

Mishandled assistive devices, including delayed and damaged wheelchairs and scooters, are another significant disability-related complaint area. From 2013 to 2022, such complaints accounted for more than 13% of all disability-related complaints that consumers filed with the Department.[16] It is either the second or third largest disability-related complaint category that the Department receives from consumers depending on the year.[17] U.S. and foreign air carriers also receive a significant number of complaints related to mishandled assistive devices directly from consumers.[18]

The Department also reviewed the data that reporting carriers[19] submit monthly to the Department on the total number of wheelchairs and scooters that they transport and the total number of those that are mishandled.[20] This reporting reveals that more than one in every 100 wheelchairs and scooters transported in the cargo compartments of domestic flights are mishandled (*i.e.,* damaged, delayed, lost, or pilfered). Below is a table that summarizes the data on mishandled wheelchairs and scooters from 2019 through June 2023.

TABLE 3—REPORTED WHEELCHAIR AND SCOOTER DATA BY YEAR

Year	Total number of wheelchairs and scooters enplaned	Total number of wheelchairs and scooters mishandled	Percent of wheelchairs and scooters mishandled per 100 enplaned
2019	685,792	10,548	1.54
2020	268,676	3,464	1.29
2021	553,969	7,239	1.31
2022	741,582	11,389	1.54
2023 (January through June)	390,200	5,361	1.37

As shown, the rate of mishandling is generally not improving, and mishandled wheelchairs and scooters remain a significant source of concern for individuals with mobility impairments. In addition, as stated above, wheelchairs and scooters are mishandled at over twice the rate of checked bags, and the consequences

[12] In 2019, carriers reported approximately 10,548 wheelchair and scooter mishandlings, equating to a mishandling rate of 1.54%. In 2022, carriers reported approximately 11,389 wheelchair and scooter mishandlings, equating to a mishandling rate of 1.54%. In 2019 and 2022, carriers reported total *baggage* mishandlings at a rate of .655%, and .63%, respectively.

[13] From 2013 to 2022, the Department received a total of 9,878 disability-related complaints from consumers. Of those, 4,144 were related to inadequate wheelchair assistance. Data regarding complaints that aviation consumers file with the Department against airlines can be found in the Department's Air Travel Consumer Report (ATCR). The ATCRs are available on the Department's aviation consumer protection website at *https://www.transportation.gov/individuals/aviation-consumer-protection/air-travel-consumer-reports.*

[14] From 2013 to 2021, U.S. and foreign carriers reported to the Department that they received a total of 278,437 disability-related complaints directly from consumers. Of those, 130,036 were related to inadequate wheelchair assistance. Data regarding disability-related complaints that aviation consumers file directly with U.S. and foreign carriers can be found in the Department's Annual Report on Disability-Related Air Travel Consumer Complaints. The Department notes that data for calendar year 2022 is not available yet. The Reports are available on the Department's aviation consumer protection website at *https://www.transportation.gov/airconsumer/annual-report-disability-related-air-travel-complaints.*

[15] In 2013, the Department received 362 inadequate wheelchair assistance complaints out of 679 total disability complaints, and airlines received 11,768 inadequate wheelchair assistance complaints out of 25,246 total disability complaints. In 2022, the Department received 838 inadequate wheelchair assistance complaints out of 2,095 total disability complaints and in 2021, airlines received 17,241 of such complaints out of 33,631 total disability complaints.

[16] From 2013 to 2022, the Department received a total of 9,878 disability-related complaints from consumer. Of those, 1,358 were related to mishandled assistive devices.

[17] From 2013 to 2017, the top disability-related complaint category was inadequate wheelchair assistance (49%), the second highest category was mishandled assistive devices (14%), and third highest category was seating accommodations (11%). From 2018 to 2022, inadequate wheelchair assistance remained the top disability-related complaint category (37%), service animals was the second highest category (23%), and mishandled assistive devices was the third highest category (14%).

[18] For example, carriers reported to the Department that in 2019, they received almost 4,000 complaints related to damage, delay, and storage of assistive devices out of 42,418 total disability complaints, and in 2022, they received over 4,140 such complaints out of 42,144 total disability complaints.

[19] ''Reporting carrier'' is defined in 14 CFR 234.2 as a U.S. carrier that accounts for at least 0.5 percent of the domestic scheduled-passenger revenues. For calendar year 2002, the reporting carriers were: Alaska Airlines, Allegiant Air, American Airlines, Delta Air Lines, Envoy Air, Frontier Airlines, Hawaiian Airlines, Horizon Air, JetBlue Airways, Mesa Airlines, PSA Airlines, Republic Airways, SkyWest Airlines, Southwest Airlines, Spirit Airlines, and United Airlines.

[20] Pursuant to 14 CFR part 234, U.S. airlines classified as ''reporting carriers'' are required to report to the Department monthly data on the number of wheelchairs and scooters they transport in the aircraft cargo compartment and the number of wheelchairs and scooters that are mishandled (*i.e.,* damaged, delayed, lost, or pilfered). This reporting requirement has applied to reporting carriers for their operations on and after December 4, 2018. In addition, reporting carriers have been required to report for the operations of their branded codeshare partners on and after January 1, 2019. Mishandled wheelchair and scooter data are published monthly in the Department's ATCR along with information on the number of disability-related complaints that aviation consumers file with the Department against airlines. The ATCRs are available on the Department's aviation consumer protection website at *https://www.transportation.gov/individuals/aviation-consumer-protection/air-travel-consumer-reports.*

that passengers with disabilities face when their wheelchairs and scooters are mishandled can be far more serious than when checked bags are mishandled.

C. ACAA Advisory Committee

In 2019, as mandated by the 2018 FAA Act, the Department established the Air Carrier Access Act (ACAA) Advisory Committee to identify and assess barriers to accessible air travel, determine the extent to which the Department is addressing those barriers, and recommend improvements. When determining the specific duties of the Committee, the Department prioritized work needed to carry out other provisions of the 2018 FAA Act. For example, as stated above, section 440 of the 2018 FAA Act directs the Department to review, and if necessary revise, applicable regulations to ensure that passengers with disabilities receive dignified, timely, and effective assistance at airports and onboard aircraft from trained personnel and to ensure that airline personnel who provide physical assistance to passengers with disabilities receive annual training that includes, as appropriate, hands-on instructions and the appropriate use of relevant equipment. Given the interest expressed by stakeholders in consulting with the Department before the Department determines if revisions to the regulations are necessary, the Department tasked the ACAA Advisory Committee with gathering information on the barriers encountered by individuals with disabilities in obtaining guide and wheelchair assistance at airports and on aircraft. The Committee was also tasked with examining airlines' disability training programs for employees and contractors who interact with the traveling public. The ACAA Advisory Committee held public meetings in March 2020 and September 2021 and submitted its final report to the Department in February 2022.[21]

In its final report, the ACAA Advisory Committee made various regulatory and non-regulatory recommendations to the Department related to assistance provided to passengers with disabilities at airports and on aircraft. Specifically, the ACAA Advisory Committee recommended that the Department ''continue to use the totality of the circumstances standard to determine if enplaning, deplaning and connecting assistance is prompt'' and ''swiftly issue its rulemaking clarifying that the [Department's] requirement to provide prompt assistance includes assistance moving within the airport when requested by or on behalf of a passenger with a disability with a departing, arriving or connecting flight.'' [22] The Committee also recommended that ''DOT codify the timeliness standard described in the Preamble of the 2008 final rule with respect to providing deplaning assistance by aisle chair (*i.e.,* aisle chair and personnel be at the arrival gate no later than as soon as other passengers have deplaned).'' [23]

The non-regulatory recommendations of the ACAA Advisory Committee include new and improved industry standards for wheelchair labelling that will facilitate safe and proper air transport, the establishment of working groups comprising disability advocates and aviation industry stakeholders to study and develop new guidance and best practices for wheelchair handling and securement, and the continuation of consumer education efforts, among other things. Furthermore, the ACAA Advisory Committee recommended that, as best practice, airlines provide hands-on training as appropriate to airline or contractor personnel who provide physical assistance to passengers with disabilities and airline or contractor personnel who handle battery-powered wheelchairs or scooters hands-on training.[24]

D. Paralyzed Veterans of America's Petition for Rulemaking

In a petition filed with the Department on December 20, 2022, Paralyzed Veterans of America (PVA) [25] stated that it believes the current ACAA regulation could be improved by: (1) mandating that only highly trained airline personnel or contractors provide boarding and deplaning assistance to individuals with mobility disabilities; (2) prohibiting carriers from transferring a passenger into an aisle chair until ready to seat the passenger on an aircraft seat or personal wheelchair; (3) requiring carriers to document and track problems that occur during the boarding and deplaning process; (4) clarifying carriers' obligation to return *all* wheelchairs and other assistive devices in the condition in which they were received; and (5) strengthening carriers' obligations in the event that they damage, lose, or otherwise mishandle a wheelchair or other assistive device. PVA elaborated that, in the event airlines mishandle an assistive device, the Department should establish a timeline to which carriers must adhere when repairing or replacing the wheelchair or other assistive device, to prevent passengers having to wait months to have their damaged wheelchair repaired or to receive a new chair. PVA also suggested that the Department require carriers to provide ''adequate interim accommodations'' after a mishandling.[26]

Separate from the Petition, DOT staff also met with PVA, at their request, on December 19, 2022, to listen to PVA's suggestions on other actions that the Department could take to improve accessibility for wheelchair users.[27] Specifically, PVA mentioned issues with loaner wheelchair vendors and options available to passengers after a mishandling. PVA proposed that airlines should offer temporary wheelchair repairs so that passengers can continue with their journeys in their own wheelchairs to the maximum extent possible until a full repair can be secured. PVA also raised issues regarding the repair claim process and noted that passengers need to be given sufficient time to review repairs carried out by airlines to determine whether the repairs are sufficient. PVA stated that often passengers would prefer to handle wheelchair repairs and replacements themselves through their own preferred vendors. PVA lastly raised other concerns related to requiring accommodations for impacted passengers should their wheelchair not fit on a flight.

III. Discussion of Proposals

A. Providing Assistance to Individuals With Disabilities

1. Safe and Dignified Assistance

The ACAA, which prohibits airlines from discriminating against an individual with a disability because of his or her disability, is celebrated as a

[21] ''Final Report: Air Carrier Access Act Committee Recommendation'' (February 4, 2022), available at *https://www.regulations.gov/document/DOT-OST-2018-0204-0040.*

[22] *Id.* at 13–14.

[23] *Id.* at 13.

[24] *Id.* at 22.

[25] Paralyzed Veterans of America is a congressionally chartered veterans service organization founded in 1946, whose members are primarily veterans of the armed forces who have experienced spinal cord injury or dysfunction. PVA is an active advocate for various issues involving the special needs of its members, including health care, research and education, benefits, and civil rights. Additional information about the organization can be found on PVA's website at *https://pva.org/about-us/.*

[26] The full Petition can be viewed in the rulemaking's docket, Docket DOT–OST–2022–0144, available online at *https://www.regulations.gov/docket/DOT-OST-2022-0144.*

[27] In accordance with the Department's rules and guidance regarding *ex parte* communications in informal rulemakings, a record of this meeting has been placed in this rulemaking's docket: *https://www.regulations.gov/document/DOT-OST-2022-0144-0003 [hereinafter PVA Meeting, December 2022].*

law that recognizes the inherent dignity of people with disabilities and their right to safe and accessible air travel. The Department's regulation implementing the ACAA requires airline personnel who deal with the traveling public to be trained to provide boarding and deplaning assistance, when applicable to their duties, in a manner that safeguards the safety and dignity of passengers.[28] Airline personnel must also train their personnel with respect to awareness and appropriate responses to passengers with a disability.[29] Despite this training requirement, disability rights advocates have reported to the Department that airlines frequently provide unsafe and undignified assistance that results in physical injuries and emotional distress to passengers with disabilities. The Department has also received consumer complaints alleging undignified assistance such as being lifted improperly causing passengers' pants to slide off in front of others resulting in embarrassment.[30] In addition, the Department has received consumer complaints alleging unsafe assistance, such as being dropped or bumped into armrests, walls, or other objects, resulting in bruises, scrapes, and other serious injuries.[31]

In this proposed rulemaking, the Department is emphasizing the importance of passengers with disabilities receiving assistance in a safe and dignified manner by proposing to explicitly include in the rule text that any assistance or accommodation required by the Department's disability regulation must be provided to individuals with disabilities in a safe and dignified manner. The Department seeks data, analysis, and recommendations from interested persons on this proposal:

- Are the terms ''safe'' and ''dignified'' easily understood by carriers and by the public?
- Should the Department include definitions for ''safe'' and ''dignified'' in part 382? If so, what should the Department consider when drafting definitions for those terms?
- Are there any other specific practices or procedures that the Department should require or prohibit to safeguard dignity and safety for passengers with disabilities?

2. Prompt Enplaning, Deplaning, and Connecting Assistance

Airlines are currently required to provide prompt enplaning and deplaning assistance, including, as needed, the use of ground wheelchairs, accessible motorized carts, boarding wheelchairs (*i.e.,* aisle chairs), and onboard wheelchairs.[32] The Department's Office of Aviation Consumer Protection has consistently interpreted the existing regulatory requirement to provide prompt enplaning and deplaning assistance to also include assistance to move within the airport because the use of an accessible motorized cart is provided as one example of how to provide prompt enplaning and deplaning assistance.[33] Moving within the airport means moving from the terminal entrance through the airport to the gate for a departing flight, moving from the gate for an arriving flight to the terminal entrance, or moving between gates to make a connection to another flight.

With respect to what constitutes ''prompt'' assistance, the Department has not previously adopted a specific maximum timeframe within which the requested assistance must be provided. Rather, except when a passenger is deplaning with the use of an aisle chair, the Department has adopted a reasonable performance-based standard and considers ''the totality of circumstances'' of each case to determine whether the requested assistance was provided promptly. The Department emphasizes that a reasonable performance standard includes carriers taking steps to ensure they have the proper staffing levels needed to handle anticipated service requests. With respect to deplaning assistance by aisle chair, the Department explained that to be prompt ''personnel and boarding chairs should be available to deplane the passenger no later than as soon as other passengers have left the aircraft.'' [34]

As stated above, untimely wheelchair assistance is one of the top categories of complaints that the Department receives from air travelers with disabilities. Further, in response to the Department's March 2022 public meeting, several comments from advocates and individuals with disabilities specifically cited experiences with excessive wait times for requested assistance, including long wheelchair service queues when arriving at airports and delayed assistance while enplaning and deplaning. These comments also mentioned that such delays can result in passengers missing flights or other important events. In addition, commenters noted that when airlines do not provide prompt assistance, passengers may feel forgotten, frustrated, and anxious. According to these commenters and complaints against airlines received by DOT, this may at times result in passengers attempting to move through the airport on their own without any assistance, which could be uncomfortable, painful, and harmful to passengers with disabilities. Some commenters added that they believe a major contributing factor for such delays was that airlines and their contractors do not have the proper staffing levels needed to handle service request volumes.

Airlines For America (A4A) and International Air Transport Association (IATA) submitted a joint comment in response to the Department's March 2022 public meeting. A4A and IATA stated that airlines provide prompt assistance as required by the Department's rules and that the appropriate determination of promptness is through a totality of the circumstances standard. A4A and IATA further explained that assistance wait times can be impacted by a variety of factors, including: whether the passenger has provided advance notice to the airline; the size of the aircraft and the number of passengers deplaning; the number of assistance requests for a given flight; unforeseen staffing and operational issues; and airport layouts.[35] The Avianca Carriers also submitted a comment in response to the Department's March 2022 public meeting.[36] Avianca Carriers stated that the services they offer to passengers with disabilities are being taken advantage of by passengers who are not qualified individuals with disabilities. They explained that such passengers put a strain on available resources to provide timely assistance and affect the wait times passengers with disabilities experience in enplaning, deplaning, and

[28] 14 CFR 382.141(a)(1)(iii).

[29] 14 CFR 382.141(a)(2).

[30] Other examples of complaints related to undignified assistance include, but are not limited to: airline personnel doubting the complainants' need for wheelchair assistance and questioning them in front of other passengers; and airline personnel making passengers with disabilities get out of wheelchairs and enplane or deplane the aircraft on their own.

[31] Other examples of complaints related to unsafe assistance include, but are not limited to: one airline personnel pushing two passengers with disabilities in wheelchairs at the same time; airline personnel not knowing how to use aisle chairs and/or how to properly strap and secure passengers to aisle chairs; and airline personnel dropping passengers with disabilities while transferring them between wheelchairs and aircraft seats.

[32] 14 CFR 382.95(a).

[33] *See* cases cited *supra* note 2.

[34] *See* Final Rule, Nondiscrimination on the Basis of Disability in Air Travel, 73 FR 27614, at 27620, May 13, 2008.

[35] *See https://www.regulations.gov/comment/DOT-OST-2022-0014-0188.*

[36] *See https://www.regulations.gov/comment/DOT-OST-2022-0014-0098.*

moving through the terminal.[37] As another reason for long wait times, Avianca Carriers noted that at certain airports, there is only one service provider approved by the airport authority. They state that this lack of competition can result in lower quality service and higher prices for airlines that contract out these services.

The Department's ACAA Advisory Committee also examined the issue of prompt enplaning, deplaning, and connecting assistance. As discussed earlier, the ACAA Advisory Committee recommended that the Department continue to use the totality of the circumstances standard to determine if enplaning, deplaning, and connecting assistance is prompt.[38] The ACAA Advisory Committee also recommended that the Department codify the timeliness standard described in the Preamble of the 2008 final rule with respect to providing deplaning assistance by aisle chair (*i.e.,* aisle chair and personnel be at the arrival gate no later than as soon as other passengers have deplaned).[39] Furthermore, the ACAA Advisory Committee recommended that the Department swiftly issue a rulemaking clarifying that the Department's requirement to provide prompt assistance includes assistance moving within the airport when requested by or on behalf of a passenger with a disability with a departing, arriving, or connecting flight.[40]

This NPRM proposes to clarify that all boarding, deplaning, and connecting assistance provided, including moving within the airport terminal, must be carried out by airlines in a ''prompt'' manner. This proposal is consistent with the Department's longstanding interpretation and practice. This proposal is also consistent with the recommendations of the ACAA Advisory Committee to issue a rulemaking clarifying that the requirement to provide prompt assistance includes assistance moving within airport when requested by or on behalf of a passenger with a disability with a departing, arriving, or connecting flight.

The Department also proposes to codify its longstanding practice of considering the totality of circumstances when evaluating whether assistance was provided in a prompt manner when deplaning assistance by aisle chair is not needed. The Department believes that this standard is appropriate given the number of factors and circumstances that may impact the timeliness of assistance, including many of those mentioned in the comments from A4A and IATA in response to the Department's March 2022 public meeting. In addition, this proposal follows the ACAA Advisory Committee's recommendation for the Department to ''continue to use the totality of the circumstances standard to determine if enplaning, deplaning and connecting assistance is prompt.''

This NPRM also proposes to codify the Department's longstanding interpretation that for deplaning assistance by aisle chair, ''prompt'' means that personnel and boarding chairs must be available to deplane the passenger no later than as soon as other passengers have left the aircraft. This proposal is in line with ACAA Advisory Committee's recommendation that the Department codify the timeliness standard described in the Preamble of the 2008 final rule with respect to providing deplaning assistance by aisle chair. The Department is also proposing that the passenger's personal wheelchair must be ready and available as close as possible to the door of the aircraft, to the maximum extent possible, except: where this practice would be inconsistent with Federal regulations governing transportation security or the transportation of hazardous materials; or when the passenger requests the wheelchair be returned at a location other than the door of the aircraft. The maximum extent possible does not mean that airlines can simply decide that it is too much work to provide passengers their own wheelchairs at the gate. It is intended to address the limited situations where it may not be possible to bring passengers' wheelchairs to the door of the aircraft. For example, if a passenger has a short connection time, then it may be necessary to transfer the wheelchair directly to the next flight. Also, the Department notes that if a passenger requests the wheelchair be returned at a location other than the door of the aircraft, an airport wheelchair must be available for the passenger's use. The Department believes that these additional proposals will reduce the amount of time that passengers with disabilities may have to sit and wait in aisle chairs, which passengers with disabilities state are uncomfortable and can completely restrict their ability to move independently.

The Department seeks data, analysis, and recommendations from interested persons on this proposal:

- Should the Department continue to consider the totality of circumstances to determine whether assistance with enplaning, deplaning, and moving within the airport (*e.g.,* moving from the terminal entrance through the airport to the gate for a departing flight, or from the gate to the terminal entrance, or moving between gates to make a connection) is provided promptly?
- With respect to deplaning assistance that requires the use of aisle chairs, should ''promptly'' continue to mean that personnel and boarding chairs must be available to deplane the passenger no later than as soon as other passengers have left the aircraft?
- For prearranged deplaning assistance that does not require the use of aisle chairs (*i.e.,* a passenger with a disability is able to walk short distances), should ''prompt'' be based on the totality of circumstances or mean that personnel and an airport wheelchair must be available to assist the passenger with moving from the gate to the terminal entrance (or moving between gates to make a connection) by the time that all other passengers have left the aircraft? Alternatively, should ''prompt'' mean that personnel and an airport wheelchair are ready and waiting for the passenger at the gate by the time the aircraft doors open and passengers *begin* to deplane? Should the fact that the individual is able to deplane the aircraft on his or her own factor into when the assistance is available?
- Is there another standard that the Department should use to define ''prompt?''

B. Handling Requirements for Wheelchairs, Mobility Aids, and Other Assistive Devices

1. Mishandling Wheelchairs, Mobility Aids, and Other Assistive Devices as a Per Se Violation

Damaged and delayed personal wheelchairs and scooters are a major concern because these devices are essential to the user's independence and mobility. Although airlines today are required to compensate passengers on domestic flights for mishandled

[37] This issue was also raised during discussions of the ACAA Advisory Committee. In its final report, the Committee states, ''In a growing number of cases, requests for wheelchair assistance are being made by non-disabled passengers. This impacts the timeliness of assistance provided to passengers with disabilities.'' *See* ''Final Report: Air Carrier Access Act Committee Recommendation'' at 17. To help address this issue, the Committee recommended that DOT post language on its website clarifying who is and is not entitled to wheelchair assistance under DOT's ACAA regulation and supported additional guidance on this point. DOT has implemented the Committee's recommendation and placed clarifying language on its website at *https://www.transportation.gov/individuals/aviation-consumer-protection/wheelchair-and-guided-assistance.*

[38] *See* ''Final Report: Air Carrier Access Act Committee Recommendation'' at 13.

[39] *Id.*

[40] *Id.* at 14.

wheelchairs up to the original price of the wheelchair,[41] this does not make passengers whole. In response to the March 2022 public meeting, the Department received many comments emphasizing that wheelchair mishandlings can lead to a multitude of problems for individuals, including fear of flying; lost wages; loss of independence; physical injury; and expensive and lengthy device repairs and/or replacements. Thus, it is of utmost importance that these assistive devices are transported safely to the passenger's destination.

The Department's disability regulation specifies that airlines must return a wheelchair or other assistive device to the passenger in the same condition in which the airline received it.[42] However, this requirement is under a heading stating, ''What other requirements apply when passengers' wheelchairs, other mobility aids, and other assistive devices must be disassembled for stowage?'' This has resulted in assertions that the requirement to return a wheelchair or other assistive device in the condition it was received only applies if an airline disassembles the wheelchair or other assistive device. In this NPRM, the Department is proposing to clarify that *any* mishandling of a passenger's checked wheelchair or other assistive device is a violation of the ACAA and is proposing to make the mishandling of a wheelchair or other assistive device a per se violation.[43] Thus, under the proposal, any checked wheelchair or other assistive device that is lost, delayed, damaged, or pilfered (*i.e.,* stolen) while under the custody and control of an airline would be considered a violation of the ACAA and part 382 regardless of the circumstances surrounding the event.

Airlines have asserted that wheelchair design and aircraft design limitations, which are factors outside of their control, can create significant issues when airline personnel or contractors handle passengers' wheelchairs and may lead to damaged devices or the inability to transport them altogether. The Department's ACAA Advisory Committee acknowledged this point and recommended the establishment of a working group ''to study how battery-powered wheelchairs and scooters could best fit and be secured within the bulk cargo compartment of both narrow-bodied aircraft and wide-bodied aircraft.'' [44] The ACAA Advisory Committee also recommended other actions to improve wheelchair handling, including an examination on improving airline checklists and forms for handling wheelchairs to make the checklists and forms more consistent across airlines and written in plain language.[45]

IATA, who has taken the lead on these initiatives, expressed concern that this rulemaking would not consider the committee's recommendations or IATA's on-going work to implement the recommendations related to wheelchair handling.[46] In December 2022, the Department met with IATA regarding this matter and informed the organization that it would consider its work to the extent that it was completed prior to the publication of this rulemaking. IATA shared its finalized wheelchair handling guidance with the Department in early 2023.[47] The Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) is also doing work in this area. Specifically, RESNA, a wheelchair standard-setting organization, recently published new wheelchair labeling and design requirements for stowage and transport in commercial aircraft.[48] The new standard includes all the information needed by airlines to create templates to request needed information from passengers regarding their wheelchairs.

This rulemaking is not in conflict with the ACAA Advisory Committee's recommendations, IATA's subsequent work, or RESNA's work. The Department encourages IATA and RESNA to continue with its valuable research and developments in this area. The Department believes that this rulemaking emphasizes the importance of their work, especially as it relates to steps that can be taken by airlines, aircraft manufacturers, and others to reduce instances of wheelchair and scooter mishandlings.

The NPRM also proposes to add a definition for ''mishandled'' as it relates to wheelchairs or other assistive devices to mean lost, delayed, damaged, or pilfered (*i.e.,* stolen), which is consistent with how the Department defines a ''mishandled checked bag'' in another aviation regulation.[49] In addition, the Department is proposing that when carriers mishandle wheelchairs and scooters, they have an obligation to inform passengers of their rights and options for moving forward. More specifically, this NPRM proposes to require airlines to immediately notify the passenger of his or her rights to: (1) file a claim with the airline; (2) receive a loaner wheelchair from the airline with certain customizations (as explained below); (3) choose a preferred vendor, if desired, for repairs or replacement of a damaged device; and (4) to have a Complaints Resolution Official (CRO) available and be provided information on how to contact the CRO. This requirement would enable impacted passengers to make informed decisions regarding remedies available to them after mishandlings and ensure that they receive prompt and proper assistance.

The Department asks for comments and data from interested parties and persons on all parts of this proposal.

- Is it reasonable to consider any mishandling of a wheelchair or other assistive device a per se violation of the ACAA? Why or why not?
- Is the proposed definition for ''mishandled'' appropriate? Why or why not?
- What, if anything, do airlines currently tell passengers when checked wheelchairs and scooters are mishandled?
- Is the Department's proposal that carriers must notify passengers of their rights and options when checked wheelchairs and scooters are mishandled sufficient? Why or why not?
- Should the proposal to notify passengers of their rights and options be limited to wheelchairs and scooters or extended to include other checked assistive devices?

2. Timely Passenger Notifications and Return of Delayed Wheelchairs or Scooters

The Department requires carriers to ''provide for the checking and timely return of passengers' wheelchairs, other mobility aids, and other assistive devices as close as possible to the door of the aircraft, so that passengers may use their own equipment to the extent possible'' as long as the practice is consistent with relevant safety and

[41] *See* 14 CFR 382.131. For international flights, the baggage provisions of the Montreal Convention, a multilateral treaty adopted by member states of the International Civil Aviation Organization (ICAO), apply.

[42] 14 CFR 382.129.

[43] ''Per se'' is a Latin phrase that means ''by itself'' or ''inherently.''

[44] *See* ''Final Report: Air Carrier Access Act Committee Recommendation'' at 12.

[45] *See id.* at 9.

[46] International Air Transport Association (IATA), Guidance on The Transport of Mobility Aids (1st ed. 2023), available online at *https://www.iata.org/*.

[47] In accordance with the Department's rules and guidance regarding *ex parte* communications in informal rulemakings, a record of this meeting has been placed in this rulemaking's docket: *https://www.regulations.gov/document/DOT-OST-2022-0144-0002*.

[48] The RESNA AT–1 Section 4 standard is available on RESNA's website at *https://www.resna.org/Portals/0/AT_AT-1_Section%204_SellSheet_9_30_21.pdf*.

[49] *See* 14 CFR 234.

security regulations.[50] However, sometimes a passenger's wheelchair or scooter is not transported on his or her flight, which means it cannot be returned to the passenger in a timely manner upon arrival. For example, an airline may lose track of a wheelchair before it makes it onto the flight, an airline may not have necessary equipment or staffing to timely load a wheelchair in the cargo, or a wheelchair may not be able to safely fit into the cargo compartment of a given aircraft. When such situations arise, it can lead to serious consequences upon arrival for passengers that rely on their personal wheelchairs and scooters. Passengers can be left stranded at airports, may be immobile until their wheelchair is returned, and may also be forced to cancel their upcoming plans and events.

As a preliminary matter, the Department believes that these situations and resulting harms could potentially be avoided if airlines provided passengers timely and accurate notifications about their checked wheelchairs and scooters during the loading and unloading process, including notification when a device cannot fit on a flight. The Department believes that this information is crucial because it not only gives passengers ''peace of mind,'' but also allows them to make informed decisions when stowage issues arise. For instance, if a passenger knows that his or her wheelchair has not been loaded on the aircraft, then he or she can make an informed decision on whether to continue the original flight without the wheelchair or to wait for another flight. A passenger also may not want to wait in an aisle chair upon arrival for reasons such as safety concerns. As such, by notifying the passenger when his or her device has been unloaded from the aircraft, the passenger can better determine when to begin the deplaning process.

Accordingly, this NPRM proposes that airlines provide timely notifications to passengers when their wheelchairs or scooters have been loaded on and unloaded from the cargo compartment of their flights. Under the proposal, airlines would also need to immediately notify the passenger upon learning that his or her wheelchair or scooter does not fit on the aircraft. The Department is not proposing a specific method that carriers should use to provide the notifications to passengers. Airlines may choose to have employees notify passengers orally, to utilize technology to provide automated notifications, or to use any other means to provide timely notifications. We note that some airlines currently use technology that tracks the location of passengers' checked baggage and provides notifications to passengers through airlines' mobile applications when checked baggage has been loaded or unloaded from aircraft. It is possible that this same technology could be used to meet the proposed requirement.

This NPRM also proposes additional safeguards should an airline fail to transport the passenger's wheelchair or scooter on his or her same flight. Specifically, this NPRM proposes the following: if a checked wheelchair or scooter is not transported on the passenger's flight, the carrier would be required to transport the device to the passenger's final destination within twenty-four (24) hours of the passenger's arrival at that destination by whatever means possible. The 24-hour requirement is meant to allow enough time for airlines to handle the logistics of the transport while also ensuring that individuals are not subjected to lengthy periods of time without their wheelchairs or scooters. The Department is also proposing to require carriers to notify passengers that they have a choice of either picking up their wheelchair or scooter at the final destination airport or having it delivered to another location based on a reasonable request made by the passenger (*e.g.,* passenger's home or hotel). The Department would consider the wheelchair or scooter to be provided to the passenger (1) when the wheelchair or scooter is transported to a location requested by the passenger if the passenger chooses to have it delivered, regardless of whether the passenger is present to take possession of the wheelchair or scooter; or (2) when the wheelchair or scooter has arrived at the destination airport, is available for pickup, and the carrier has provided notice to the passenger of the location and availability of the wheelchair or scooter for pickup if the passenger chooses to pick it up. The Department envisions ''by whatever means possible'' to include the carrier seeking out other commercial passenger flights or freight flights that could accommodate the device and other ground shipping options that would result in prompt delivery to the passenger. The carrier would be required to cover costs for the transport.

The Department seeks comments and data in response to the following questions related to this NPRM proposal:

- What are airlines' current practices regarding tracking wheelchairs and scooters and providing updates and notifications to passengers on the status of their wheelchairs and scooters?
- Should the Department consider requiring airlines to provide other status updates to passengers about their checked wheelchairs and scooters (*e.g.,* stowage location of the passenger's wheelchair or scooter on the flight)? Should the requirement to provide status updates extend to other assistive devises that are checked in cargo or be limited to wheelchairs and scooters?
- What are airlines' current policies and practices when a passenger's wheelchair or scooter does not fit in the cargo compartment?
- Are there any other concerns or factors that the Department should consider when a passenger's wheelchair or scooter does not fit in the cargo compartment? Because learning at the airport that a wheelchair or scooter does not fit in the cargo compartment can disrupt travel plans of passengers, should carriers be required to provide the dimensions of their cargo compartments prior to travel to any passenger who shares that he or she will be traveling with a personal wheelchair or scooter? The Department notes that airlines are already required to notify passengers, on request, of any limitations on the availability of storage facilities, in the cabin or in the cargo bay, for mobility aids or other assistive devices commonly used by passengers with a disability.[51]
- What are airlines' current policies and practices regarding delayed wheelchairs and scooters?
- How do airlines deliver delayed wheelchairs and scooters to passengers and what are the average associated costs? How long does it typically take to get a delayed wheelchair or scooter to the passenger?
- Do airlines cooperate with each other when seeking out alternative flights to transport a delayed wheelchair or scooter to an impacted passenger? Is the cooperation based on whether airlines have an interline agreement with one another?
- How do airlines communicate and provide updates to passengers regarding the status of their delayed wheelchairs and scooters? Is there a preferred or best method for contact, such as by email, text message, or phone call?
- In situations where the wheelchair of a passenger with disabilities is delayed or damaged and the passenger is waiting for his/her wheelchair or a loaner wheelchair at the airport, should airlines be required to provide safe and adequate seating options that will accommodate the passenger? What

[50] 14 CFR 382.125(b).

[51] *See* 14 CFR 382.41(d).

types of seat options would accommodate passengers with disabilities while they wait in the airport for their wheelchairs and what are the costs and logistics associated with having these options available at the airports?

- Should the Department consider any other factors or standards when determining what is meant by device delivery to the ''passenger's final destination''? And if so, why?
- If an individual with a disability incurs additional, associated costs because a wheelchair or scooter is delayed, should the airline be responsible for reimbursing the individual for those costs? What are these potential costs? What documentation should individuals provide to airlines to substantiate these costs? Should there be a limit to the airlines' liability?

3. Prompt Repair or Replacement of Lost, Damaged, or Destroyed Wheelchairs or Scooters

Under existing regulations, in the event that a passenger's wheelchair is damaged, lost, or destroyed by an airline on a domestic flight, the normal baggage liability limits under 14 CFR part 254 do not apply and instead carriers must use the original purchase price of the device as the basis for calculating compensation.[52] For international flights, the provisions of the Montreal Convention, a multilateral treaty adopted by member states of the International Civil Aviation Organization (ICAO), apply. Under the Montreal Convention, airlines must pay up to a limit of 1,131 Special Drawing Rights (SDR) [53] for an assistive device that is lost, damaged, or destroyed. Beyond the compensation requirement, the Department's disability regulation is silent regarding options and other necessary accommodations for passengers with disabilities after their wheelchairs and scooters have been mishandled, including how repairs and replacements should be best handled based on the passenger's specific circumstances and needs. The Department believes revisions to its regulation are needed to ensure that passengers impacted by mishandlings are not further plagued by unnecessary delays, undesirable repair and replacement processes, and additional resulting costs.

When a passenger's personal wheelchair or scooter is mishandled by an airline, carriers have different methods and policies for coordinating wheelchair repairs and replacements. For example, after a passenger files a claim, some carriers may require a passenger to use a wheelchair repair vendor chosen or contracted by the carrier, while others may allow the passenger to find a vendor on their own for the handling of the repair or the replacement. When the carrier chooses the vendor, the vendor may then reach out directly to the passenger to provide their assessment and price quote. In some cases, if the damage is very severe or if the vendor no longer repairs the passenger's specific wheelchair model, then a full replacement may be necessary.

However, individuals with disabilities state that the wheelchair repair and replacement process is not so simple and can often be messy, lengthy, and frustrating when carried out by the airline. Individuals with disabilities and disability organizations assert that individuals with disabilities would strongly prefer to take their damaged wheelchair to a vendor that they trust, already have a relationship with, and/or know will be able to timely repair their exact wheelchair model, rather than having to rely on the airline to coordinate. They also assert that there may be unnecessary delays in the process and a lack of transparency when the airline acts as the middleman. We note that in these situations, the passenger will have better information about their personal wheelchair and their personal circumstances, including whether they may have a backup wheelchair readily available to use while the repairs are carried out. Accordingly, we agree that individuals with disabilities need to have a greater say in this process and require more flexibility when determining how their damaged wheelchairs and scooters will be repaired or replaced in order to ensure their non-discriminatory treatment.

As such, in this NPRM, the Department is proposing to require airlines to provide two separate options to a passenger who files a claim with the airline after his or her personal wheelchair or scooter has been lost, damaged, or destroyed: (1) the passenger can elect for the carrier to handle the repair or replacement of the device; or (2) the passenger can elect to use the passenger's preferred vendor to repair or replace the device. If the passenger selects the first option, the carrier must repair or replace the device, depending on the severity of the damage; return the device within a reasonable timeframe; and pay the cost of the repairs or replacement. The Department has not proposed to define a specific ''reasonable'' timeframe, as we acknowledge that there are many different factors that could impact the timing for this process, including the complexity of the necessary repairs, the availability of parts needed for the repairs, and fluctuating turnaround times for vendors. In any case, airlines should work directly with the passenger and immediately initiate the repair/replacement process once a passenger has filed a claim.

If the passenger selects the second option, the carrier would be required to promptly transport the wheelchair or scooter to the passenger's preferred vendor, unless the passenger has indicated that he or she will arrange for the transport themselves. The carrier would be required to cover the cost of this transport. The carrier would also be required to pay the wheelchair vendor directly for the cost of repairs or replacement within a reasonable timeframe. To ease the burden on the passenger and expedite the process, the Department is proposing that the billing for the repairs or replacement go directly to the airline so the passenger is not forced to front the costs. The Department seeks comments on this point and whether direct billing to the airline may cause any unforeseen issues. Similar to the proposed requirements of the first option, and to account for varying circumstances outside the control of airlines, the Department proposes to use a ''reasonable'' standard for timeliness of payment rather than defining specific deadlines. If a dispute were to arise between the parties over the cost of the repairs or replacement, the passenger should submit quotes, receipts, or other similar documentation to the airline to prove or substantiate costs. The Department does not anticipate that fraudulent claims for repairs or replacements will be a significant issue under this proposal.

Under both proposed options, if a replacement is necessary due to the severity of the damages or because the device was lost, the provided replacement device must have equivalent or greater function and safety as the individual's original device.

The Department also seeks feedback, comments, and data on the following questions related to this NPRM proposal:

[52] *See* 14 CFR 382.131.

[53] The SDR was created by the International Monetary Fund (IMF) and is defined as ''equivalent to the value of a basket of world currencies. The SDR itself is not a currency but an asset that holders can exchange for currency when needed. The SDR serves as the unit of account of the IMF and other international organizations.'' *See https://www.imf.org/en/About/Factsheets/Sheets/2023/special-drawing-rights-sdr.* As of November 15, 2023, one SDR was roughly equivalent to $1.32 USD in value.

• Are there sufficient vendors available to repair or replace passengers' personal wheelchairs or scooters? What is the average turnaround time once the vendor has the passenger's wheelchair in its possession?

• What are airlines' current policies and procedures related to replacing, repairing, and/or reimbursing passengers for damaged wheelchair and scooters, including how costs are determined? Do disputes arise between passengers and airlines over the costs to repair or replace damaged wheelchairs and scooters? If they do, how are these disputes resolved?

• Should the Department consider stricter and detailed timelines rather than using a reasonableness standard to which airlines must adhere when handling wheelchair and scooter repairs and replacement?

• Are certain types of wheelchairs and scooters no longer repairable or replaceable?

• Are all repairs handled only by Durable Medical Equipment (DME) suppliers and should the Department address this issue in rulemaking? Would proprietary agreements or right-to-repair laws impact this or any of the current proposals set forth in this NPRM?

• Do disputes arise between passengers and airlines over whether a repair or a full wheelchair or scooter replacement is necessary based on the level of damage to the wheelchair or scooter? If they do, who should be responsible for ultimately determining whether a wheelchair or scooter is ''fixable''? If the carrier (or the carrier's chosen vendor) makes the determination, should the passenger then be given an opportunity to independently review their determination and carry out their own assessment?

• Does travel insurance cover wheelchairs or scooters if lost or damaged during a trip? If so, how much of the cost to replace wheelchairs or scooters can be recouped? Should the airline's cost be limited to whatever is not paid by the travel insurance, or is baggage/wheelchair travel insurance often secondary (*i.e.,* consumer must first file a claim with airline before filing a travel insurance claim)?

• PVA previously stated that once an airline has completed a wheelchair repair and returned the device to the passenger, the passenger needs to be given an opportunity to test the wheelchair and confirm whether the repairs are indeed adequate.[54] Do airlines currently provide passengers the opportunity to test a repaired wheelchair or scooter to confirm whether the repairs are adequate? Should the NPRM's first option include a ''testing period''? If so, how long should the passenger have to carry out this review and determine whether additional repairs by the airline are necessary?

• PVA also advocated for an additional option where, at the passenger's request, an airline would be required to provide a minor ''temporary wheelchair repair'' that is essentially sufficient to get the passenger out the door of the airport with their personal wheelchair so that they can continue on with their journey as planned to the maximum extent possible and seek out a ''full repair'' at a later time and date.[55] Does this option seem reasonable to airlines and to passengers with disabilities? Would airlines logistically be able to do this? What exactly would a ''temporary wheelchair repair'' entail, and is this something that wheelchair repair vendors already offer/provide? If required, would airlines then need to have a vendor on-site at the airport to handle this? And if so, what types of costs would be associated with this option?

4. Loaner Wheelchair Accommodations

The Department currently does not specify what accommodations, beyond compensation for a wheelchair, airlines must provide to passengers with disabilities in the event that an airline mishandles a passenger's personal wheelchair or scooter. Nevertheless, many carriers already secure loaner wheelchairs for impacted passengers and cover the associated costs of the loaner since it can take up to weeks or even months for repairs on a damaged wheelchair to be completed or for a replacement wheelchair to be ready after a passenger's wheelchair is destroyed. In their joint public comment to the March 2022 public meeting, IATA and A4A state that a loaner manual wheelchair may cost roughly $250 per month while a high-end powered wheelchair may cost $4,500 for a three-month rental.

Advocates and individuals with disabilities state that the loaners received from airlines are not always safe and adequate for the individual user. They assert that loaner wheelchairs may not be suitable for certain users if they are not customized to meet the individual's functional needs and personal specifications. It appears that this problem arises most often when more complex, battery-powered devices are mishandled. If the loaner wheelchair is not suitable for the user's needs (*e.g.,* proper cushioning, back support, leg and arm rests), it can lead to discomfort, pain, pressure sores, and other injuries and medical complications. This point is especially important because passengers may be spending extended periods of time with these loaner wheelchairs while they await repairs or a replacement wheelchair or scooter.

The Department recognizes that loaner wheelchairs are vital for passengers whose wheelchairs and scooters are delayed, damaged, or lost. Loaner wheelchairs give those passengers the ability to continue their normal daily lives, to the maximum extent possible, until they can get their personal wheelchair back or secure an adequate replacement. Accordingly, this NPRM proposes to require carriers to consult with passengers on a loaner wheelchair that best meets the passenger's physical and functional needs, and to pay for that wheelchair, so passengers are able to safely use the loaner wheelchair while waiting for their mishandled personal devices to be returned, repaired, or replaced. The Department believes this is a necessary accommodation when carriers mishandle passengers' personal wheelchairs.

The Department also recognizes that it may not be possible to secure a loaner wheelchair that is identical to the passenger's personal wheelchair. Under this NPRM, the airlines would be required to provide, upon request, functional and safety-related customizations (*e.g.,* changing cushions; adding lumbar support seat attachment; adjusting the headrest, armrest, or footrest) on loaner wheelchairs, to the extent possible, to ensure passengers can safely use them.

The Department also seeks feedback, comments, and data on the following questions related to this NPRM proposal:

• What types of customizations should be required under this proposal, how much such customizations generally cost, and how quickly such customizations can be completed?

• Can the loaner wheelchair requirements be easily implemented by airlines and do they meet the needs of individuals with disabilities who experience wheelchair mishandlings?

• If an individual with a disability incurs additional, associated costs because the loaner wheelchair provided by the airline restricts his or her mobility or independence, should the airline be responsible for reimbursing the individual for those costs? What are

[54] *See* PVA Meeting, December 2022, *supra* note 27.

[55] *Id.*

these potential costs? What documentation should individuals provide to airlines to substantiate these costs? Should there be a limit to the airlines' liability?

C. Enhanced Training for Certain Airline Personnel and Contractors

The Department is proposing to enhance its existing training requirements for airline employees and contractors who physically assist passengers with mobility disabilities or handle passengers' wheelchairs or scooters. Currently, the Department requires airline personnel and their contractors who deal with the traveling public to receive general training on awareness and communication as well as training tailored to their job duties within 60 days of assuming their duties.[56] Airline personnel and contractors who deal with the traveling public include but are not limited to customer service agents, flight attendants, reservation agents, and wheelchair attendants. The required training consists of training to proficiency on the requirements of the Department's disability regulation in part 382 and other relevant Federal regulations, as well as on the airline's procedures to implement these requirements, including how to properly and safely operate equipment used to accommodate passengers with a disability, as appropriate to the employee's or contractor's duties.[57] In addition, airline personnel and contractors who deal with the traveling public must be trained ''with respect to awareness and appropriate responses to passengers with a disability, including persons with physical sensory, mental, and emotional disabilities, including how to distinguish among the different abilities of individuals with a disability.'' [58] They must also be trained to recognize requests for communication accommodation from individuals whose hearing or vision is impaired.[59] Further, airline and contractor personnel who provide boarding and deplaning assistance must be trained to proficiency on the use of boarding and deplaning equipment and the ''boarding and deplaning assistance procedures that safeguard the safety and dignity of passengers.'' [60] Refresher training to public contact personnel and contractors is required every three years, at a minimum.[61]

In their joint comment to the Department's March 2022 Meeting, A4A and IATA state that their member airlines agree that there is value in and benefits to hands-on training. They state that resulting improvements can include familiarity with mobility aids lifting procedures, especially with heavy items and for employee safety, battery safety and regulatory limitations, communication with passengers, and the application of airline procedures. They assert that their member airlines provide hands-on training ''in various forms as needed by and tailored to the circumstances, including instructor-led courses, on-the-job training, initial training courses, and special training events at stations.'' Further, airlines commented that any new training requirements should not be prescriptive so that training can be adapted based on input from the disability community, while also best meeting the airline's operational needs. They state that ''adaptability is even more critical given the incredible diversity of our passengers, their assistance needs, aircraft, airport configurations, and employees, as well as the growing complexities and peculiarities of mobility aids.'' They also raise concerns with the associated costs, including pay and travel costs to attend; costs of training equipment; instructor costs; and lost revenues because front-line employees are taken away from their operational duties. They commented that in consideration of few violations in relation to a high number of successfully assisted passengers, recurrent hands-on training should only be required for employees who are involved in a mishandling incident or who fail to follow airline procedures.

However, individuals with disabilities and advocacy organizations strongly believe that current airline training programs related to disability assistance at airports and on aircraft are insufficient. In response to the Department's March 2022 Meeting, the Department received numerous comments asserting that airline personnel and contractors are not adequately trained in providing physical assistance and with handling assistive devices. Further, in a letter to the Secretary, dated December 2, 2022, PVA states, ''Too often the process of boarding and deplaning an aircraft causes a wheelchair user to experience physical injury and emotional stress. The wheelchair attendants who assist passengers with mobility impairments frequently demonstrate that they are not able to safely assist a passenger who must board and deplane using an aisle chair. In addition, passengers who use wheelchairs often experience great fear, often well founded, that their assistive device will be delayed, damaged, or lost when they arrive at their destination.'' [62]

In a supplemental comment to the Department, PVA points to multiple publications and studies that concluded either that training in this area could be improved or that part 382 could be enhanced with greater training specificity.[63] PVA states that ''it is imperative that wheelchair attendants be fully trained and able to subsequently demonstrate to a superior on the job their ability to properly assist a passenger throughout the airport, as needed, and on and off the aircraft.'' PVA also states that ''attendants should be required to complete refresher training every six months and be recertified yearly on the job by a superior in order to remain qualified for providing aisle chair assistance.'' [64]

Individuals with disabilities and other advocacy organizations also assert that airline personnel and contractors lack general knowledge regarding the proper handling of personal wheelchairs and other assistive devices and fail to follow instructions from passengers. They note that wheelchairs can be damaged when proper lifting and securement points on the wheelchair are not located and used, when a wheelchair is tilted or loaded while lying on its side, and when the airline does not have loading equipment robust enough to support a given a wheelchair. Additionally, as noted in the ACAA Advisory Committee's work, improper handling and loading techniques can also injure airline personnel and contractors.[65]

The Department's proposals for enhanced training focus on the training given to airline personnel and contractors who provide physical assistance to passengers with mobility-related disabilities and who handle passengers' wheelchairs and other assistive devices. Given the nature of their job duties and responsibilities, it is essential that these airline employees and contractors receive more extensive training. Inadequate training of these employees and contractors could result in harm to passengers with disabilities

[56] 14 CFR 382.141 and 14 CFR 382.143(a)(4).

[57] 14 CFR 382.141(a)(1).

[58] 14 CFR 382.141(a)(2).

[59] 14 CFR 382.141(a)(3).

[60] 14 CFR 382.141(a)(1)(iii).

[61] 14 CFR 382.141(a)(5).

[62] PVA's full Letter can be viewed in the rulemaking's docket, Docket DOT–OST–2022–0144, available online at *https://www.regulations.gov/docket/DOT-OST-2022-0144.*

[63] The full Comment can be viewed in the rulemaking's docket, Docket DOT–OST–2022–0144, available online at *https://www.regulations.gov/docket/DOT-OST-2022-0144.*

[64] *Id.*

[65] *See* Report of the Subcommittee on Stowage of Assistive Devices, available at *https://www.regulations.gov/document/DOT-OST-2018-0204-0021.*

and costly damages to passengers' wheelchairs. The Department is proposing more thorough, frequent, and hands-on training of these employees and contractors. The Department believes that these training enhancements would improve the safety and dignity of passengers with disabilities; prevent wheelchairs from being damaged, delayed, or lost; and improve the overall services of airlines.

When determining that enhanced training in these two areas is needed, the Department was persuaded by comments from passengers with disabilities and advocates, the disability complaints that the Department receives against airlines and that airlines receive directly from passengers, and the data on mishandled wheelchairs. Disability rights advocates have long argued that airline personnel and contractors are not careful, rush assistance, use improper equipment and techniques, and do not follow the passenger's instructions because of lack of adequate training. The Department has also reviewed numerous complaints where, during the boarding and deplaning process, passengers who require transfer assistance are dropped to the ground; bumped into arm rests, overhead compartments, and other objects; and held or lifted inappropriately. This unsafe assistance has resulted in passengers with disabilities sustaining pain and injuries and experiencing stress and embarrassment. The Department has also reviewed numerous complaints and comments where passengers' wheelchairs are damaged during airline handling, including broken joysticks, cracked frames, and bent axles. As mentioned, airline reports to the Department indicate that airlines are mishandling thousands of wheelchairs and scooters each year.

The Department also found persuasive IATA's recommendations regarding airline employee training and has incorporated key topics and suggestions into the NPRM's training proposal.[66] IATA's guidance contains a list of topics that should be covered during training, at a minimum, including: disability awareness and communications; transfer techniques for passengers; safe lifting techniques for mobility aids; safe and common methods for reducing size and weight of mobility aids; securement techniques in the bulk cargo compartment; and mobility aid reassembly and reconfiguration steps. IATA also notes: ''In addition to general training, airlines and airport operators should ensure that they train and maintain a continuous competence of their employees and contractors who are required to handle mobility aids. This will include procedures for preparing, securing, carrying and stowing of mobility aids for air transport.''

In addition to stakeholder comments and recommendations, the Department carefully considered the following sources when examining regulatory enhancements for training: research carried out by Volpe on problems associated with passenger transfers and wheelchair mishandlings;[67] training requirements set forth in the Canadian Transportation Agency's disability regulations and related guidance and recommendations;[68] and PVA's comments submitted to the Department in support of additional and more robust training requirements for wheelchair assistants and ramp personnel.[69] The Department also considered the recommendation of the ACAA Advisory Committee that ''as best practices, airlines provide hands-on training as appropriate for airline or contractor personnel who handle battery-powered wheelchairs or scooters; hands-on training be provided as appropriate to airline personnel or contractors who provide physical assistance to passengers with disabilities; and airlines involve individuals with disabilities, whether it is through their advisory board or external organizations, in their training programs.''[70]

The Department proposes to require employees and contractors who provide physical assistance to passengers with mobility-related disabilities receive hands-on training covering safe and dignified physical assistance, including transfers to and from personal or airport wheelchairs, aisle chairs, and aircraft seats; proper lifting techniques to safeguard passengers; how to troubleshoot common challenges when providing physical assistance; and proper use of equipment used to physically assist passengers with disabilities. These personnel would also be required to receive other training covering collecting and sharing of passenger information needed to ensure safe, dignified, and prompt physical assistance, such as Special Service Request (SSR) codes.

Like the proposals for airline employees and contractors who provide physical assistance to passengers with mobility-related disabilities, the Department is proposing more thorough and hands-on training for employees and contractors who handle passengers' wheelchairs and other mobility aid devices. Specifically, the Department is proposing hands-on training covering common types of wheelchairs and other mobility aids and their features; airport and airline equipment used to load and unload wheelchairs and other mobility aids; and methods for safely moving and stowing wheelchairs, including lifting techniques, wheelchair disassembly, reconfiguration, and reassembly, and securement in the cargo compartment of the aircraft. Personnel who handle passengers' wheelchairs and other mobility aid devices would also be required to receive other training covering the collecting and sharing of information regarding a passenger's wheelchair or other mobility aid, including using any airline wheelchair handling form(s) that may exist, to ensure the safe and proper handling of such assistive devices.

This NPRM proposes to define ''hands-on training'' to mean training that is received by an employee or contractor where the employee or contractor performs a task, function, or procedure that would be part of his or her normal duties in a controlled/simulated environment and with the use of a suitable life-sized model or equipment, as appropriate. A suitable life-sized model could be a full-body mannequin or a person, such as an instructor or volunteer. Hands-on training could also be supplemented with related on-the-job training as appropriate for wheelchair handlers.

Further, the Department proposes to amend when initial and refresher training is provided to personnel who provide physical assistance to passengers with mobility-related disabilities and personnel who handle passengers' wheelchairs and other mobility aid devices. Instead of initial training being required within 60 days of assuming their duties, as is currently the case, we are proposing that this newly required training, including hands-on training, be provided prior to the covered airline employees and

[66] International Air Transport Association (IATA), Guidance on The Transport of Mobility Aids (1st ed. 2023), available online at *https://www.iata.org/*.

[67] *See* ''Ensuring Safe Accommodations for Air Travelers with Disabilities Using Wheelchairs: Regulatory Impact Analysis,'' available in the rulemaking's docket, Docket DOT–OST–2022–0144.

[68] *See* Canadian Transportation Agency (CTA), Personnel Training for the Assistance of Travelers with Disabilities: A Guide, available online at *https://otc-cta.gc.ca/*. *See also* CTA, Best Practices for Interacting with Persons with Disabilities: A Guide, available online at *https://otc-cta.gc.ca/*.

[69] The full Comment can be viewed in the rulemaking's docket, Docket DOT–OST–2022–0144, available online at *https://www.regulations.gov/docket/DOT-OST-2022-0144*.

[70] *See* ''Final Report: Air Carrier Access Act Committee Recommendation'' at 22.

contractors assuming their duties. Also, instead of refresher training being required at least once every three years as is the case today, the Department is proposing to mandate that these airline employees and contractors receive such training at least once every twelve months. The Department believes that annual refresher training is necessary for such personnel to maintain a high level of skill and to stay up-to-date on related procedures and technologies. The Department notes that airlines would also continue to be required to train these personnel with respect to awareness of different types of disabilities and appropriate communications and interactions with passengers with disabilities.

The Department notes further that proposed changes in the disability-related training requirements for all other personnel (*e.g.,* ticket counter agents and telephone reservation agents) are minor. The proposed revisions are primarily formatting and language changes to promote consistency throughout the regulation, without expanding the airlines' obligations. The Department is also proposing changes to clarify the training requirements that would apply based on the duties of the airline employee or contractor. The more substantive change is the proposed requirement for airlines to consult with disabilities rights organizations not only regarding their initial training programs, as required today, but also to consult with such organizations when making changes to disability training programs and related policies and procedures that are expected to have a significant impact on assistance provided to individuals with disabilities. The ACAA Advisory Committee had recommended that airlines consult with disability rights organizations if changing or enhancing their disability training program.[71] The Department believes that many carriers are already taking such actions and that this proposed additional requirement would not impose a significant burden on carriers.

Although not included in the proposed rule text, the Department is also considering whether airlines should be required to designate wheelchair experts and transfer experts who could be consulted in the event that a complex issue or problem arises while handling a passenger's personal wheelchair or while physically assisting a passenger with a disability. These experts would have a similar role to Complaint Resolution Officials (CROs) and would require training above and beyond the proposed requirements set forth in this NPRM for related personnel. The Department seeks public comments on this idea and whether such a requirement would be reasonable and beneficial for consumers and on challenges that carriers may have.

In drafting the NPRM, the Department focused on key issues that must be addressed when training personnel and contractors who provide physical assistance to passengers with mobility-related disabilities and who handle passengers' wheelchairs and other assistive device rather than creating overly prescriptive standards. The Department intentionally provides flexibility for airlines, within the parameters set forth in the proposal, to develop training programs that best suit their needs, the needs of their employees and contractors, and the needs of their customers. The NPRM also recognizes the importance of hands-on training and more frequent training for these personnel. The Department believes this approach would prevent or significantly reduce wheelchair mishandlings and injuries to individuals with disabilities.

The Department seeks data, analysis, and recommendations from interested persons on this proposal:

- Are the proposed amendments to the training requirements in part 382 sufficient to address concerns and inadequacies with current training practices?
- Should the Department impose more specific training requirements rather than identifying the topics that airlines must cover as part of the training? For example, the Department is aware of existing standards for caregivers to provide safe patient assistance involving lifting and transferring. Would it be more beneficial to require training standards such as these? And if so, which ones should be considered and what are the associated costs of the training?
- Are the proposed topics to be covered when training personnel and contractors who handle passengers' wheelchairs sufficient (*i.e.,* common types of wheelchairs and other mobility aids and their features; airport and airline equipment used to load and unload wheelchairs and other mobility aids; and methods for safely moving and stowing wheelchairs, including lifting techniques, wheelchair disassembly, reconfiguration, and reassembly, and securement in the cargo compartment of the aircraft)? If not, what additional topics should the Department consider requiring?
- Are the proposed topics to be covered when training personnel and contractors who provide physical assistance to passengers with disabilities sufficient (*i.e.,* safe and dignified physical assistance, including transfers to and from personal or airport wheelchairs, aisle chairs, and aircraft seats; proper lifting techniques to safeguard passengers; how to troubleshoot common challenges when providing physical assistance; and proper use of equipment used to physically assist passengers with disabilities)? If not, what additional topics should the Department consider requiring?
- Is the Department's proposed definition of hand-on training reasonable? What other factors, if any, should the Department consider when defining hand-on training?
- Is the proposed frequency of recurrent training (at least once every 12 months) reasonable? Should the Department require more frequent training (*e.g.,* once every six months) or less frequent training (*e.g.,* once every 18 months or once every 24 months)? What are the costs and logistical considerations associated with such training for airline employees and contractors?
- Should other types of airline employees and contractors be subject to the enhanced training requirements set forth in this proposal? For example, reservation agents gather information about consumers' travel needs and ticket counter agents handle consumer inquires, including disability related accommodation requests. Also, while managers may not directly assist individuals with disabilities or handle wheelchairs, they are often responsible for overseeing the airlines' processes and personnel. Is the existing requirement that individuals who deal with the traveling public be trained as appropriate to their duties sufficient?

D. Improved Standards for Onboard Wheelchairs (OBWs)

The Department requires airlines to equip certain aircraft[72] with onboard wheelchairs (OBWs), *i.e.,* wheelchairs that are used to transport an individual with a mobility disability between an aircraft seat and an aircraft lavatory. In 2008, the Department set minimum safety and accessibility standards for OBWs.[73] Then, in 2023, the Department

[71] ''Final Report: Air Carrier Access Act Committee Recommendation'' at 18.

[72] If an aircraft has more than 60 seats and an accessible lavatory, then the Department requires that airline to equip the aircraft with an OBW. 14 CFR 382.65(a). The Department also mandates that if aircraft being used for a flight has more than 60 passenger seats and a passenger requests an OBW, then the airline must provide an OBW even if the aircraft does not have an accessible lavatory. 14 CFR 382.65(b).

[73] 14 CFR 382.65(c).

required enhanced performance standards for the OBWs to be used on single-aisle aircraft that have 125 or more passenger seats that are delivered on or after October 2, 2026.[74] At that time, the Department also required airlines that replace an OBW on such aircraft to replace it with an improved OBW that provides the significant safety and accessibility improvements to individuals with disabilities, because of the Department's view that if improved OBWs are available on the market then they should be the ones purchased. The Department is now proposing to require these improved performance standards for all OBWs.

More specifically, in this NPRM, the Department is proposing to expand the usage of improved OBWs in several different ways. First, the Department proposes that if carriers purchase an OBW after October 2, 2026, then they must purchase an OBW meeting the Department's improved standards. Again, if improved OBWs are available on the market, then the Department believes that they should be the ones purchased, whether as a replacement or as an addition. Second, the Department proposes that any aircraft with 60 or more passenger seats and an accessible lavatory (*e.g.,* twin aisle aircraft) delivered after October 2, 2026, be equipped with an OBW meeting the Department's improved standards. This approach would ensure that the benefits afforded by these new OBWs reach more individuals with disabilities without imposing costs all at once on airlines. Finally, the Department is proposing that, by October 2, 2031, all OBWs meet the Department's new safety and accessibility standards. The Department presumes that by this date that there would be only a few OBWs that do not meet the improved standard but believes that it is important to have a date certain for all OBWs to meet this standard.

This rulemaking proposes that the OBW standards be improved to include the following:

(1) the ability to maneuver both forward and backward through the aircraft aisle by an attendant;

(2) seat height that aligns with the height of the aircraft seat to facilitate a safe transfer;

(3) wheels that lock in the direction of travel, and that lock in place so as to permit safe transfers, with any other moving parts capable of being secured such that they do not move while it is occupied and maneuvered;

(4) design such that it does not tip or fall in any direction under normal operating conditions when occupied for use;

(5) a padded seat and backrest and must be free of sharp or abrasive components;

(6) arm supports that are sufficiently structurally sound to permit transfers and repositionable so as to allow for unobstructed transfers; adequate back support; torso and leg restraints that are adequate to prevent injury during transport; and a unitary foot support that provides sufficient clearance to traverse the threshold of the lavatory and is repositionable so as to allow for unobstructed transfer, with all restraints operable by the passenger;

(7) ability to maneuver in a forward orientation partially into at least one aircraft lavatory to permit transfer from the on-board wheelchair to the toilet;

(8) ability to maneuver into the aircraft lavatory without protruding into the clear space needed to completely close the lavatory door; and

(9) prominent display of instructions for proper use.

This is consistent with the standards set for the OBWs to be used on single-aisle aircraft that have 125 or more passenger seats that are delivered on or after October 2, 2026.[75]

The Department expects that, by October 2, 2026, OBW manufacturers will have available OBWs that meet the Department's new standards. If that should not be the case, the Department proposes to require airlines to acquire an OBW that complies with as many of the proposed requirements as are available. Under this proposal, airlines would not be held responsible for the failure of third parties to develop and deliver OBWs that meet these requirements. The Department is proposing to require airlines to inform the Department if OBW meeting all the requirements are not available. This is consistent with the requirements for airlines who will be acquiring OBWs for large single aisle aircraft delivered after October 2, 2026.

The Department seeks data, analysis, and recommendations from interested persons on the proposed OBW requirements, including the costs and benefits. We specifically solicit comment on the following topics:

- *OBW Wheelchair Stowage Space:* What should happen if the improved OBWs do not fit within the pre-existing stowage space?[76] Should airlines be required to expand the existing on-board wheelchair stowage space of the aircraft, or modify the interior arrangement of the lavatory or the aircraft to enable the OBW to fit? Would it be sufficient if the Department requires airlines to stow the OBW in another space that exists (*e.g.,* an overhead compartment) where it could fit consistent with FAA safety standards as the Department did for OBWs stowed on large single-aisle aircraft? What obstacles, if any, would apply to stowing OBWs onboard aircraft that are subject to this new rulemaking?
- *Dates for Improved OBWs:* The Department has proposed that any aircraft with 60 or more passenger seats and an accessible lavatory delivered after October 2, 2026, be equipped with the improved OBW. The Department already requires that large single aisle aircraft delivered after this same date have improved OBWs. Is the date selected reasonable? Why or why not? The Department also proposes a date certain, five years after October 2, 2026, when all OBWs must meet the improved performance standard. Is this date reasonable? If not, what would be a more reasonable time frame, and what would be the costs and benefits of that approach?
- *Availability of Improved OBWs in Marketplace:* In this NPRM, the Department is proposing to require airlines to acquire OBWs that comply with as many of the proposed safety and accessibility requirements as are available. The Department is also proposing that airlines inform the Department that an OBW meeting that a safety or accessibility requirement is unavailable if that is the case. Is this the right approach? Should the Department require airlines to retain records of the unavailability of OBWs that meet all the proposed safety and accessibility requirements instead of informing DOT? What would be the costs and benefits of any such modifications?

E. Size Standard for Lavatories on Twin-Aisle Aircraft

The Department is seeking comment on whether it should update the accessibility requirements for twin-aisle aircraft given the new requirements that apply to large single-aisle aircraft ordered after October 3, 2033, or delivered after October 2, 2035. Currently, twin-aisle aircraft must

[74] 14 CFR 382.65(e).

[75] 14 CFR 382.65(e)(1–9).

[76] For new single-aisle aircraft over 125 seats that are delivered after October 2, 2026, carriers are not required to expand the existing FAA-certificated on-board wheelchair stowage space of the aircraft, or modify the interior arrangement of the lavatory or the aircraft, in order to stow the improved OBW. However, if the OBW does not fit within the original stowage space, and another space exists (*e.g.,* an overhead compartment) where it could fit consistent with FAA safety standards, then the carrier must stow it in that space and must request any necessary FAA approval to do so. 14 CFR 382.65(f).

include at least one lavatory of sufficient size to permit a qualified individual with a disability to enter, maneuver within as necessary to use all lavatory facilities, and leave, by means of the aircraft's on-board wheelchair, while affording privacy equivalent to that afforded ambulatory users.[77] This requirement has been in place for U.S. carriers since 1992, and for foreign carriers since 2010.[78]

More recently, the Department set new size standards for lavatories on new *single*-aisle aircraft. Specifically, new single-aisle aircraft with an FAA-certificated maximum seating capacity of 125 seats or more in which lavatories are provided, shall include at least one lavatory of sufficient size to permit a qualified individual with a disability equivalent in size to a 95th percentile male to approach, enter, maneuver within as necessary to use all lavatory facilities, and leave, by means of the aircraft's on-board wheelchair, in a closed space that affords privacy equivalent to that afforded to ambulatory users. The lavatory must *also* be large enough to permit an assistant equivalent in size to a 95th-percentile male to assist the individual with a disability.[79] This ''95/95 Standard'' applies to new single-aisle aircraft that were originally ordered after October 3, 2033, or delivered after October 2, 2035, or are part of a new type-certificated design filed with the FAA or a foreign carrier's safety authority after October 2, 2024.[80]

The 95/95 standard is larger than the size standard for twin-aisle aircraft. Specifically, an accessible single-aisle aircraft lavatory must be large enough to accommodate a large male passenger *and* a large male attendant; in contrast, the twin-aisle standards do not specify the size of the passenger, and do not mention attendants at all. As a result, it is possible that accessible lavatories for twin-aisle aircraft may in the near future be smaller than the accessible lavatories found on single-aisle aircraft. This result is counterintuitive, particularly because twin-aisle aircraft are generally used for the longest international flights.[81] Accordingly, the Department is considering whether to explicitly mandate the 95/95 standard, or a similar standard, for accessible twin-aisle aircraft lavatories.

It is possible that, in practice, accessible twin-aisle aircraft lavatories today already meet the 95/95 standard, even if they are not required to do so. More generally, it is possible that twin-aisle lavatories today are adequate to accommodate passengers with disabilities, OBWs, and their attendants, even without a 95/95 standard. The Department solicited data on some of these questions during the rulemaking process for accessible lavatories on single aisle aircraft.[82] The Department received some comments, but not significant data, in response to these questions. Airbus indicated generally that its twin-aisle solutions comply with current part 382.[83] Boeing indicated that its accessible twin-aisle lavatories do not necessarily meet the 95/95 standard, but ''are considered large enough to accommodate a disabled passenger in a wheelchair with an attendant behind the closed lavatory door.'' [84] However, disability advocates commented that the experience of their members is mixed, with not all twin-aisle lavatories being large enough to accommodate an attendant.[85] A4A and IATA commented that they are not aware of a material number of complaints regarding the size of accessible twin-aisle lavatories. This is the Department's experience as well.

The Department solicits data and comment on all aspects of this question, including but not limited to the following:

- Is the 95/95 standard, which has been adopted for future new single-aisle aircraft lavatories, appropriate for twin-aisle aircraft lavatories? Why or why not?
- To what extent do twin-aisle aircraft lavatories currently meet the 95/95 standard? If current twin-aisle lavatories do not meet the 95/95 standard, what standards do they meet in terms of accommodating large passengers, OBWs, and large attendants?
- What would be the incremental benefits for passengers with disabilities, and other passengers, in adopting a 95/95 standard? Would lavatories meeting the 95/95 standard require a larger footprint than those found on current twin-aisle aircraft? If so, what are the costs associated with installing a lavatory meeting this larger footprint?
- If the Department adopted a 95/95 standard for twin-aisle aircraft, what would be an appropriate time frame for implementation? What factors should the Department consider when setting an implementation time frame? [86]

F. Refund of Fare Difference When Passengers' Wheelchairs Cannot Fit on Preferred Flight

The Department is soliciting comment on whether it should require U.S. and foreign air carriers to refund the difference between the fare on a flight a passenger who uses a wheelchair took and the fare on a flight that the passenger would have taken if his or her wheelchair had been able to fit in the cabin or cargo compartment of the aircraft.[87] Currently, airlines are required to stow assistive devices in the baggage compartment of an aircraft if an approved stowage area is not available in the cabin or the device cannot fit in the cabin.[88] Such devices, including wheelchairs, scooters, and other mobility aids, must be given priority over other cargo and baggage. However, if a device still cannot be transported in this manner due to its size or for other safety concerns, then the airline is not required to transport it.

The Department notes that in 2020, the Canadian Transportation Agency issued a regulation that states that if a carrier is unable to transport a passenger's mobility aid device on a flight, then the carrier is required to advise the passenger of alternative trips provided by the same carrier to the same destination and offer booking for no additional cost (if desired).[89]

The ACAA Advisory Committee explored options to address instances

[77] 14 CFR 382.63(a)(1–2).

[78] 14 CFR 382.63(d).

[79] 14 CFR 382.64(a)(1–2).

[80] 14 CFR 382.64(c).

[81] Analysis of Bureau of Transportation Statistics T–100 All Segment data. Data retrieved in Aug. 2023.

[82] *See* 87 FR 17,222 (''The Department currently requires airlines to ensure that at least one lavatory on twin-aisle aircraft is accessible. To what extent do accessible lavatories on twin-aisle aircraft meet the needs of passengers with disabilities, particularly passengers with mobility impairments? Are accessible lavatories on twin-aisle aircraft large enough to accommodate an assistant to assist the passenger with transfers between the OBW and the toilet?'').

[83] Comment of Airbus at p.3, available at *https://www.regulations.gov/comment/DOT-OST-2021-0137-0302.*

[84] Comment of Boeing at p.5, available at *https://www.regulations.gov/comment/DOT-OST-2021-0137-0357.*

[85] Comments of PVA at 10, available at *https://www.regulations.gov/comment/DOT-OST-2021-0137-0350;* NDRN at 2, available at *https://www.regulations.gov/comment/DOT-OST-2021-0137-0353;* Cure SMA at 2, available at *https://www.regulations.gov/comment/DOT-OST-2021-0137-0186.*

[86] For context, we note that the Department's original rule for accessible twin-aisle aircraft was issued after a negotiated rulemaking in 1988. The rule, effective in January 1990, applied to twin-aisle aircraft ordered after April 5, 1990, or delivered after April 5, 1992. The Department expanded this rule to foreign air carriers on May 13, 2008; it applied to new aircraft that were ordered after May 13, 2009, or delivered after May 13, 2010. *See* 14 CFR 382.63(d); 87 FR 17216–17217.

[87] United Airlines has committed to refund, upon request, the fare difference when a passenger's preferred flight cannot accommodate his or her wheelchair and the flight that he or she travels on with the wheelchair is more expensive, among other things. *See https://www.transportation.gov/briefing-room/us-department-transportation-announces-united-airlines-will-implement-industry.*

[88] *See* 14 CFR 382.125.

[89] *See* Accessible Transportation for Persons with Disabilities Regulations, SOR/2019–244 (Can.).

when a passenger's assistive device does not fit or cannot be safely carried on his or her flight. Airlines stated to the ACAA Advisory Committee that they make efforts to ensure that larger assistive devices, such as wheelchairs or scooters, can travel on the same flight as the passengers when feasible.[90] Airlines explained that they may disassemble certain components of the wheelchairs and deploy specialized equipment and ramps to assist in the handling and loading of very heavy devices to, among other things, ensure that larger wheelchairs and scooters can be travel on the same flight as the passenger. The ACAA Advisory Committee found that even with such efforts, the accommodation of large assistive devices may be impractical or impossible if they cannot fit on the types of aircraft operated by the carrier.

The ACAA Advisory Committee considered recommending to the Department that it require airlines to accommodate a passenger with a disability and his or her mobility aid device on another flight offered by that same airline at no additional cost. Airlines voiced several logistical concerns with these options. They said that some carriers may operate limited fleets of aircraft, or only one type of aircraft, with similar cargo doors and cargo compartments. The ACAA Advisory Committee also considered recommending that the Department require airlines accommodate a passenger on another airline that can transport the passenger and his or her wheelchair or scooter at no additional cost. Airlines asserted that this option would be costly and complex because it would necessitate airlines coordinating and reimbursing other airlines for transporting a passenger and their mobility aid devices. Ultimately, the ACAA Advisory Committee did not make a recommendation with respect to this issue.

PVA has separately urged the Department to require airlines to offer alternative transportation that meets the accessibility needs of the passenger with a disability when the original flight does not.[91] PVA explains that this may be a new flight on the booked airline or another airline, or other mode of transportation, *i.e.,* a train, bus, or rental car. PVA adds that the Department should mandate that the airlines cover any additional or increased cost of the alternative transportation, such as the cost to fly on another airline or travel on other mode of transportation and overnight accommodations necessary for transportation of the passenger with a disability and their travel companions.

The Department recognizes that passengers who use larger wheelchairs and scooters may not be able to select certain flight options because their wheelchairs may not be able to fit or cannot be safely carried on certain aircraft. The Department further acknowledges that in some instances, passengers who use larger wheelchairs and scooters may be able to select only a more expensive flight because a cheaper flight option uses an aircraft that cannot accommodate their wheelchair or scooter. Individuals with disabilities should not have to pay higher prices for air fares only because their assistive devices cannot be transported on certain flights.

The Department solicits data and comments on all aspects of this question, including but not limited to the following:

- How often does this issue arise for individuals with disabilities who travel by air with their personal wheelchairs and scooters?
- Do any airlines currently offer individuals with disabilities rebooking on another flight on the same airline at no additional cost when their wheelchairs or scooters cannot be carried on their originally booked flights and if the subsequent flights have higher fares?
- Do any airlines currently offer individuals with disabilities alternate transportation on other airlines or other modes of transportation (*i.e.,* a train, bus, or rental car) at no additional cost when their personal wheelchairs and scooters cannot be carried on their originally booked flights? If so, how does this process work? Do airlines book the alternate transportation on other airlines or other modes of transportation or do individuals with disabilities have to first purchase the alternate transportation and then ask the airline to reimburse the costs? If not, what are the reasons or challenges to providing this accommodation?
- Do airlines currently offer individuals with disabilities the lower fare if the individual points out that he or she was unable to take the flight with a lower fare because his or her wheelchair could not fit in the cargo compartment?
- Should the Department require airlines to rebook individuals with disabilities on another flight on the same airline at no additional cost when their wheelchairs or scooters cannot be carried on their originally booked flights? Should this be limited to flights on the same airline or should it be expanded to flights on other airlines or other modes of transportation (*i.e.,* a train, bus, or rental car)? Should this only apply to instances when wheelchairs or scooters cannot fit on the passenger's flight or should it apply to other types of disability accommodations (*e.g.,* the passenger's originally booked flight cannot accommodate the passenger's seating needs; or the passenger's originally booked flight does not have an accessible lavatory)?
- Should the Department require airlines to refund the fare difference when passengers must book more expensive flights because their personal wheelchairs and scooters cannot be carried on cheaper flights? If so, in what situations should airlines be required provide refunds of the fare difference? Should airlines only provide a refund of the fare difference when the passenger's preferred flight itinerary that cannot accommodate the wheelchair and the more expensive flight itinerary that can accommodate the wheelchair have the same origin and destination, are on the same day, and have the same number of legs, stops, and connection points (if applicable)? Should airlines be required to provide a refund of the fare difference even if the preferred flight itinerary and the more expensive flight itinerary are not on the same day or do not have the same number of legs, stops, or connection points are different? Should a refund of a fare difference be required only if the preferred flight and the more expensive flight are offered by the same airline?
- Should airlines be permitted to require passengers to take certain steps to obtain a refund of the fare difference? If so, what are those steps? What types of proof or documentation, if any, should passengers with disabilities be required to submit to airlines when requesting a lower fare or seeking a reimbursement of the fare difference?
- Once a passenger completes the necessary steps and submits all the necessary documentation, should airlines be required to provide passengers a refund of the fare difference within seven days of receiving necessary documentation when ticket was purchased by credit card? Why or why not?
- What are the potential benefits of these proposals to passengers who use wheelchairs and scooters?
- What challenges would airlines experience if this were a requirement?

[90] *See* Report of the Subcommittee on Stowage of Assistive Devices, available at *https://www.regulations.gov/document/DOT-OST-2018-0204-0021.*

[91] *See* PVA's comments filed on the Department's NPRM on Airline Ticket Refunds and Consumer Protections, Docket DOT–OST–2022–0089, available online at *https://www.regulations.gov/comment/DOT-OST-2022-0089-5262.*

Could this process be automated, or would an airline agent need to review each case and process the reimbursement? What would the associated costs be for implementing this proposal?

IV. Severability

The overall purpose of this proposed rule is to increase access to safe and dignified air travel for individuals with disabilities. The first series of proposals clarifies the Department's current regulation by specifying when safe, adequate, and prompt assistance is required to be provided by airlines. The second series of proposals improves accommodations for individuals with disabilities in the event of a wheelchair mishandling by an airline. Such proposals include notifying passengers when their wheelchairs have been loaded onto and off of the aircraft, strict timeframes for the return of a delayed wheelchair, improved options for passengers when coordinating wheelchair repairs and replacements, and new requirements for loaner wheelchairs. The third series of proposals requires airline personnel that provide physical assistance to individuals with disabilities and that handle passengers' personal wheelchairs to receive annual hands-on training. The final series of proposals requires new improved performance standards for OBWs on twin-aisle aircraft and aircraft with 60 or more seats.

This entire suite of measures is designed to ensure accessibility and equality in air travel for individuals with disabilities and to address the ongoing and serious difficulties that wheelchair users experience today when traveling, including wheelchair damage and personal injuries. However, the Department finds that these proposals can operate independently from each other, if necessary, and are intended to operate as such. For example, updated training standards can operate separately from remedies for passengers following wheelchair mishandlings even though they could impact one another.

In the event that a court were to invalidate one or more of this proposed rule's unique provisions as finalized, the Department's intent is that the remaining provisions should remain in effect to the greatest extent possible.

V. Regulatory Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

Executive Order 12866 (''Regulatory Planning and Review''), supplemented by Executive Order 13563 (''Improving Regulation and Regulatory Review''), directs Federal agencies to propose or adopt a regulation only after making a reasoned determination that the benefits of the intended regulation justifies its costs. The Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action under Executive Order 12866 and requires an assessment of potential benefits and costs. Accordingly, the Department has prepared a regulatory impact analysis (RIA) for the proposed rule, summarized in this section and available in the docket. Table 4 below provides a summary of the costs and benefits of this proposed rulemaking.

TABLE 4—SUMMARY OF ECONOMIC IMPACTS DUE TO PROPOSED RULE

[2023 Dollars (millions)]

Proposed provision	Costs/benefits	Total 20-year value discounted at 7 percent	Total 20-year value discounted at 3 percent	Annualized value, discounted at 7 percent	Annualized value, discounted at 3 percent	Unquantified
§ 382.141 Enhanced Training Requirements for Certain Airline Personnel and Contractors.	Costs	($108.6)	($165.5)	($5.4)	($8.2)	N/A.
	Benefits	119.0	170.9	6.0	8.6	Avoided Injuries and Fatalities.
§ 382.141 Enhanced Wheelchair Handling Training Component.	*Costs*	*(39.7)*	*(60.6)*	*(2.0)*	*(3.0)*	*N/A.*
	Benefits	*119.0*	*170.9*	*6.0*	*8.6*	*Avoided Injuries, Avoided Loss of Mobility.*
§ 382.141 Enhanced Transfer Assistance Training Component.	*Costs*	*(68.9)*	*(104.9)*	*(3.4)*	*(5.2)*	*N/A.*
	Benefits	*0*	*0*	*0*	*0*	*Improved Dignity; Avoided Injuries.*
§ 382.65 Onboard Wheelchair Performance Requirements.	Costs	(13.0)	(17.8)	(0.7)	(0.7)	N/A.
	Benefits	0	0	0	0	Avoided Injuries and improved lavatory accessibility.
§ 382.11 Safe and Dignified Assistance for Passengers with Disabilities; § 382.89 Prompt Boarding, Deplaning, and Connecting Assistance for Passengers with Disabilities.	Costs	0	0	0	0	N/A.
	Benefits	0	0	0	0	Clarifies existing requirements.
§ 382.3 Definition of a Mishandled Wheelchair, Scooter, or Other Assistive Device; § 382.125(e) Timely Passenger Notifications; § 382.130(a–b) Wheelchair Mishandling As a Per Se Violation; § 382.130(c) Ensuring That a Delayed Wheelchair Is Returned as Quickly as Possible; 382.130(d) Options for Passengers When a Wheelchair Has Been Lost, Damaged, or Pilfered; 382.130(e) Loaner Chair Accommodations.	Costs	0	0	0	0	N/A.
	Benefits	0	0	0	0	Clarifies existing requirements and/or captures existing practice; Passenger is notified of rights in event of mishandling; Passenger is provided opportunity to change plans if wheelchair does not fit on plane.
Total Costs		121.6	183.3	6.1	8.9	N/A.
Total Benefits		119.0	170.9	6.0	8.6	N/A.
Net Benefits		−2.6	−12.4	−0.1	−0.34	N/A.

This NPRM proposes to clarify airlines' requirements under part 382 by codifying the Department's longstanding view that all assistance, including physical assistance, provided to individuals with disabilities by airlines in accordance with part 382 must be conducted in a safe and dignified manner. It also proposes to codify the Department's interpretation of the word ''prompt.'' We do not expect these proposed provisions to have a cost impact because airlines are already making efforts to comply with the Department's longstanding view and interpretation.

This NPRM proposes to clarify that *any* mishandling of a checked wheelchair or other assistive device by an airline, regardless of whether the device was disassembled or not, is a violation of the ACAA and subject to potential enforcement, which may include the imposition of civil penalties. This NPRM also proposes to require airlines to inform passengers of their rights following wheelchair and scooter mishandlings. We do not expect these proposals to have a cost impact because it primarily clarifies the Department's longstanding interpretation of the requirement that airlines must return wheelchairs and other assistive devices to passengers in the condition they received them.

This NPRM also includes new proposed requirements for airlines to provide timely stowage notifications to wheelchair and scooter users, to ensure that mishandled wheelchairs and scooters are swiftly returned, repaired, or replaced by airlines, and to provide individuals impacted by mishandlings with greater flexibility in choosing vendors for wheelchair repairs and replacements without having to foot the bill themselves. This NPRM also addresses the critical need for loaner wheelchair accommodations while individuals wait for their mishandled wheelchairs. We do not expect these proposed provisions to have a cost impact because airlines assert that they are already providing these services to passengers, including when wheelchairs and other mobility aids are mishandled. Even so, there is significant benefit to consumers from establishing standards that all carriers must meet and that the Department is able to enforce if any carrier fails to do so. As for passenger notifications, airlines may be able to leverage existing systems to meet the proposed requirements.

In addition, this NPRM proposes enhancements to the part 382 airline training requirements by expanding training for airline personnel that provide physical assistance to passengers with disabilities and personnel that handle passengers' personal wheelchairs and other mobility aids. The proposal would generally require more frequent, hands-on training for such personnel on several different job-related subjects, among other things. The RIA estimates the annualized cost of the proposed training requirements to be $5.4 million at a 7 percent discount rate or $8.2 million at a 3 percent discount rate.

The annualized benefit of the proposed training requirements is estimated to be $6.0 million at a 7 percent discount rate or $8.6 million at a 3 percent discount rate. The proposal is expected to reduce injuries, including fatalities, sustained by passengers with disabilities, the frequency and degree of damages to wheelchairs due to mishandling, and the associated hardships and expenses that passengers encounter when wheelchairs are mishandled.

Furthermore, this NPRM proposes to expand the circumstances under which airlines would be required to use OBWs meeting new safety and accessibility standards. The annualized cost for this proposal is expected to be $700,000 at a 7 percent discount rate or $700,000 at a 3 percent discount rate. The quantified benefits of this proposal, which are avoided injuries, are estimated on a breakeven basis. The RIA estimates that the proposal would need to result in 24 avoided injuries annually in 2023 growing to 48 avoided injuries annually in 2043 to cover costs. Additional unquantified benefits include improved lavatory accessibility.

The Department further notes that the greater convenience, safety, and accessibility provided by all the proposed provisions could lead passengers with disabilities to increase their use of air travel, either by switching from slower modes of travel or by making more long-distance trips. The potential increase in travel and the associated increase in consumer surplus have not been quantified in this analysis.

Executive Orders 12866 and 13563 also require agencies to provide a meaningful opportunity for public participation. Accordingly, the Department has asked commenters to answer a variety of questions to elicit practical information about relevant data and analytic approaches, as described in the section titled, ''Discussion of proposed rule text and requests for data and comments.'' The Department also specifically requests comments and data on the unquantified benefits mentioned in the table above. Additional questions on this can be found in the full-length RIA. These comments will help the Department further evaluate the economic effects of the proposed rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. A direct air carrier or foreign air carrier is a small business if it provides air transportation only with small aircraft (*i.e.,* aircraft with up to 60 seats/18,000-pound payload capacity).[92] In 2023, 29 air carriers meeting these criteria reported passengers traffic data to the Bureau of Transportation Statistics.[93] As described in the Initial Regulatory Flexibility Analysis (IRFA), the primary regulatory initiatives discussed in this NPRM would apply to carriers that operate aircraft with FAA-certificated maximum capacity of more 19 or more seats. This group of impacted air carriers includes small businesses. There would be an impact on those carriers due to proposed increased training requirements for personnel who provide physical assistance and perform wheelchair handling. The RIA estimates that the proposed rule would require two additional hours of training per year for personnel performing physical assistance or performing wheelchair handling (§ 382.141). However, the cost of two additional hours of wages per year per employee is expected to be nonsignificant. Assuming relevant personnel work 2,000 hours per year on average (40 hours per week times 50 weeks per year), a two-hour increase is just 0.1% increase in labor costs for the impacted roles which would be a much smaller percentage of all labor costs and an even smaller percentage of all operating costs. The other provisions of the rule either apply only to carriers that operate aircraft with more than 60 seats and are therefore not small businesses, or do not impose costs. Accordingly, the Department does not believe that the NPRM would have a significant impact on a substantial number of small entities. However, we invite comment on the potential impact of this rulemaking on small entities as

[92] 14 CFR 298.2.

[93] Bureau of Transportation Statistics. No date. ''Aviation Support Tables: Carrier Decode'' *https://www.transtats.bts.gov/DL_SelectFields.aspx?gnoyr_VQ=GDH&QO_fu146_anzr=N8vn6v10%20f722146%20gnoyr5.* To access the data, download all field names, filter to only show ''Carrier_Group_New'' code 5, sort by End_Date, and count entries with no End_Date value.

described in the IRFA posted to the rulemaking docket.

C. Executive Order 13132 (Federalism)

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This notice does not propose any provision that: (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government; (2) imposes substantial direct compliance costs on State and local governments; or (3) preempts State law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the topics on which the Department is seeking comment would significantly or uniquely affect the communities of the Indian Tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), no person is required to respond to a collection of information unless it displays a valid OMB control number. This NPRM does not propose any new information collection burdens.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) 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 section, of $100 million or more (adjusted annually for inflation) in any one year. As described elsewhere in the preamble, this proposed rule would have no such effect on State, local, and Tribal governments or on the private sector. Therefore, the Department has determined that no assessment is required pursuant to UMRA.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this proposed action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR. 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS).[94] In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS.[95] Paragraph 4.c.6.i of DOT Order 5610.1C categorically excludes ''[a]ctions relating to consumer protection, including regulations.'' This rulemaking concerns consumer and civil rights protection for individuals with disabilities. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking. The Department welcomes public comment on potential environmental impacts, including climate change impacts, that may result from this rulemaking.

H. Rulemaking Summary, 5 U.S.C. 553(b)(4)

As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found in the Abstract section of the Department's Unified Agenda entry for this rulemaking at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=2105-AF14* and in the docket for this rulemaking at *https://www.regulations.gov/docket/DOT-OST-2022-0144/unified-agenda.*

List of Subjects in 14 CFR Part 382

Air carriers, Civil rights, Consumer protection, Individuals with Disabilities, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Transportation proposes to amend 14 CFR part 382 as follows:

[94] *See* 40 CFR 1508.4.

[95] *Id.*

PART 382—NONDISCRIMINATION ON THE BASIS OF DISABILITY IN AIR TRAVEL

■ 1. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 41705.

Subpart A—General Provisions

■ 2. Amend § 382.3 by adding in alphabetical order the definitions of ''Hands-on training'' and ''Mishandled'' to read as follows:

§ 382.3 What do the terms in this rule mean?

* * * * *

Hands-on training means training that is received by an employee or contractor where the employee or contractor performs a task, function, or procedure that would be part of his or her normal duties in a controlled/simulated environment and with the use of a suitable life-sized model or equipment, as appropriate.

* * * * *

Mishandled means lost, delayed, damaged, or pilfered.

* * * * *

Subpart B—Nondiscrimination and Access to Services and Information

■ 3. In § 382.11, redesignate paragraph (b) as paragraph (c) and add new paragraph (b) to read as follows:

§ 382.11 What is the general nondiscrimination requirement of this part?

* * * * *

(b) As a carrier or an indirect carrier, the assistance you provide with respect to this part must be performed in a safe and dignified manner.

* * * * *

Subpart E—Accessibility of Aircraft and Service Animals on Aircraft

■ 4. Amend § 382.65 by revising paragraph (h) to read as follows:

§ 382.65 What are the requirements concerning on-board wheelchairs?

* * * * *

(h)(1) If you replace an on-board wheelchair supplied on aircraft with an FAA-certificated maximum seating capacity of 125 or more after October 2, 2026, then you must replace it with an on-board wheelchair that meets the standards set forth in paragraph (e) of this section.

(2) After October 2, 2026, if you purchase or otherwise obtain a new on-board wheelchair for use on aircraft with more than 60 passenger seats, it must meet the standards set forth in paragraph (e) of this section.

(3) Any on-board wheelchair supplied on aircraft with an FAA-certificated maximum seating capacity of more than 60 passenger seats and that has an accessible lavatory and that was delivered after October 2, 2026, must meet the standards set forth in paragraph (e) of this section.

(4) After October 2, 2031, any on-board wheelchair that you provide for passengers' use on aircraft with more than 60 passenger seats must meet the standards set forth in paragraph (e) of this section.

(5) For purposes of paragraphs (h)(2) through (4), you must acquire OBWs that comply with as many of the proposed safety and accessibility requirements in paragraph (e) of this section as are available. You must inform the Department at the address cited in 14 CFR 382.159 that an on-board wheelchair meeting that requirement is unavailable, if that is the case.

Subpart G—Boarding, Deplaning, and Connecting Assistance

■ 5. In Subpart G, add § 382.89 to read as follows:

§ 382.89 How timely must the service required under this Subpart be provided by carriers to passengers with disabilities?

(a) As a carrier, the assistance you provide with respect to this subpart must be performed in a prompt manner.

(b) Whether the assistance is prompt is dependent on the totality of the circumstances, except, for as set forth in paragraph (c) of this section.

(c) Prompt assistance for a person who uses a boarding chair (*i.e.,* aisle chair) in deplaning means:

(1) personnel and boarding chair must be available to deplane the passenger when the last passenger who did not request deplaning assistance departs the aircraft; and

(2) the passenger's personal wheelchair must be available as close as possible to the door of the aircraft to the maximum extent possible, except where this practice would be inconsistent with Federal regulations governing transportation security or the transportation of hazardous materials; or when the passenger requests the wheelchair be returned at a location other than the door of the aircraft. If the passenger requests the wheelchair be returned at a location other than the door of the aircraft, an airport wheelchair must be available as close as possible to the door of the aircraft for the passenger's use.

■ 6. In § 382.95, revise paragraph (a) to read as follows:

§ 382.95 What are carriers' general obligations with respect to boarding and deplaning assistance?

(a) As a carrier, you must provide or ensure the provision of assistance requested by or on behalf of passengers with a disability, or offered by carrier or airport operator personnel and accepted by passengers with a disability, in enplaning and deplaning. This assistance must include, as needed, the services of personnel and the use of ground wheelchairs, accessible motorized carts, boarding wheelchairs, and/or on-board wheelchairs where provided in accordance with this part, and ramps or mechanical lifts.

* * * * *

Subpart I—Stowage of Wheelchairs, Other Mobility Aids, and Other Assistive Devices

■ 7. In § 382.125, add new paragraph (e) to read as follows:

§ 382.125 What procedures do carriers follow when wheelchairs, other mobility aids, and other assistive devices must be stowed in the cargo compartment?

* * * * *

(e) You must provide timely notifications to passengers when their wheelchairs and scooters have been loaded and stowed in the cargo compartment and unloaded and retrieved from the cargo compartment. In the event that a passenger's wheelchair or scooter does not fit into the cargo compartment, you must immediately notify the impacted passenger.

■ 8. In Subpart I, add § 382.130 to read as follows:

§ 382.130 What are the handling requirements for wheelchairs and other assistive devices and what obligations apply when wheelchairs or other assistive devices are mishandled?

(a) The mishandling of a passenger's checked wheelchair or other assistive device is a violation of the Air Carrier Access Act within the meaning of 49 U.S.C. 41705.

(b) In the event of a mishandling of a wheelchair or scooter, you must immediately notify the impacted passenger of his or her rights to file a claim with the carrier, to receive a loaner wheelchair or scooter from the carrier with certain customizations described in paragraph (e) of this section, to choose a preferred vendor for repairs or replacement of the device, and to have a Complaints Resolution Official (CRO) available and be provided information on how to contact the CRO.

(c)(1) When a checked wheelchair or scooter has been delayed, you must ensure that the device is transported to the passenger's final destination within 24 hours of the passenger's arrival by whatever means possible.

(2) You must provide passengers a choice between picking up the wheelchair or scooter at the passenger's final destination airport or having the wheelchair or scooter delivered to another location based on a reasonable request by the passenger, such as the passenger's home or hotel. The wheelchair or scooter is considered to be provided to the passenger when the wheelchair or scooter is transported to a location requested by the passenger if the passenger chooses to have it delivered, regardless of whether the passenger is present to take possession of the wheelchair or scooter; or when the wheelchair or scooter has arrived at the destination airport, is available for pickup, and the carrier has provided notice to the passenger of the location and availability of the wheelchair or scooter for pickup if the passenger chooses to pick it up.

(d) When a checked wheelchair or scooter has been lost, damaged, or pilfered, you must give the passenger the following options:

(1) The passenger may file a claim with the carrier and elect for the carrier to handle the repair or replacement of the wheelchair or scooter. If the passenger selects this option, you must repair or replace the wheelchair or scooter, with a device of equivalent or greater function and safety, within a reasonable timeframe and pay the cost of repairs or replacement; or

(2) The passenger may file a claim with the carrier and elect to use the passenger's preferred vendor to repair or replace the wheelchair or scooter. If the passenger selects this option, you are responsible for promptly transporting the damaged wheelchair or scooter to the passenger's preferred vendor, unless the passenger has indicated that he or she will arrange for the transport themselves, and for paying the cost of transport and repairs or replacement, with a device of equivalent or greater function and safety, within a reasonable period.

(e) While the passenger is waiting for his or her mishandled personal wheelchair or scooter to be returned, repaired, or replaced, you must use your best efforts to work with the passenger and to provide an adequate loaner wheelchair or scooter that meets the passenger's functional and safety-related needs, to the maximum extent possible. You must pay for the cost of the loaner wheelchair or scooter.

Subpart J—Training and Administrative Provisions

■ 9. Revise § 382.141 to read as follows:

§ 382.141 What training are carriers required to provide for their personnel (i.e., employees and contractors)?

(a) As a carrier that operates aircraft with 19 or more passenger seats, you must ensure training, meeting the requirements of this paragraph, for all personnel who interact with the traveling public or who handle passengers' assistive devices, as appropriate to the duties of each employee or contractor.

(1) *General.* You must ensure training to proficiency concerning:

(i) The requirements of this part and other applicable Federal regulations affecting the provision of air travel to passengers with a disability;

(ii) Your procedures, consistent with this part, concerning the provision of air travel to passengers with a disability, including the proper and safe operation of any equipment used to accommodate passengers with a disability; and

(iii) Your procedures that safeguard the safety and dignity of passengers with disabilities when providing service required under this part.

(2) *Communication.* You must ensure employees and contractors who interact with the traveling public are trained with respect to awareness of different types of disabilities, including how to distinguish among the differing abilities of individuals with a disability.

(i) You must ensure such employees and contractors are trained on appropriate ways to communicate and interact with passengers with a disability, including persons with physical, sensory, mental, and emotional disabilities (*e.g.,* speaking to the individual with a disability instead of to the travel companion).

(ii) You must also ensure such employees and contractors are trained to recognize requests for communication accommodation from individuals whose hearing or vision is impaired and to use the most common methods for communicating with these individuals that are readily available, such as writing notes or taking care to enunciate clearly, for example. Training in sign language is not required. You must also train these employees to recognize requests for communication accommodation from deaf-blind passengers and to use established means of communicating with these passengers when they are available, such as passing out Braille cards if you have them, reading an information sheet that a passenger provides, or communicating with a passenger through an interpreter, for example.

(3) *Physical Assistance.* You must ensure that employees and contractors who provide physical assistance to passengers with disabilities who use wheelchairs and other assistive devices are trained in the matters listed in paragraphs (a)(1) and (2) of this section, and the following:

(i) Hands-on training concerning safe and dignified physical assistance, including: transfers to and from personal or airport wheelchairs, aisle chairs, and aircraft seats; proper lifting techniques to safeguard passengers; how to troubleshoot common challenges in providing physical assistance; and proper use of equipment used to physically assist passengers with disabilities; and

(ii) Other training concerning the collecting and sharing of passenger information, such as Special Service Request (SSR) codes, needed to ensure safe, dignified, and prompt physical assistance.

(4) *Handling of Wheelchairs and Other Mobility Aids.* You must ensure that employees and contractors who handle passengers' wheelchairs and other mobility aid devices are trained in the matters listed in paragraphs (a)(1) and (2) of this section, as appropriate to the duties of each person, and the following:

(i) Hands-on training concerning common types of wheelchairs and other mobility aids and their features, airport and airline equipment used to load and unload wheelchairs and other mobility aids, and methods for safely moving and stowing wheelchairs, including lifting techniques, wheelchair disassembly, reconfiguration, and reassembly, and securement in the cargo compartment of the aircraft; and

(ii) Other training concerning the collecting and sharing of information regarding a passenger's wheelchair or other mobility aid, including using any airline wheelchair handling form(s) that may exist, to ensure the safe and proper handling of such assistive devices.

(5) *Consulting With Disability Rights Organizations.* You must consult with organizations representing individuals with disabilities in your home country when developing your training program and your policies and procedures. When making changes to such training programs and related policies and procedures that will have a significant impact on assistance provided to individuals with disabilities, you must consult with organizations representing individuals with disabilities who would be affected by those changes. If such organizations are not available in your home country, you must consult with individuals with disabilities and/or international organizations representing individuals with disabilities.

(6) *Training Frequency.* You must ensure that all personnel who are required to receive training receive refresher training on the matters covered by this section, as appropriate to the duties of each employee and contractor, as needed to maintain proficiency. The training program must describe how proficiency will be maintained.

(i) All personnel who provide physical assistance to passengers with disabilities must receive the training described in paragraph (a)(3) of this section, prior to assuming their duties and at least once every twelve months thereafter.

(ii) All personnel who handle passengers' wheelchairs and other mobility aid devices must receive the training described in paragraph (a)(4) of this section, prior to assuming their duties and at least once every twelve months thereafter.

(iii) All other personnel must receive training prior to assuming their duties and at least once every three years thereafter.

(7) *Contractors.* You must provide, or ensure that your contractors receive, training concerning travel by passengers with a disability. This training is required only for those contractors who interact directly with the traveling public or who handle passengers' assistive devices, and it must be tailored to the employees' functions. Training for contractors must meet the requirements of paragraphs (a)(1) through (6) of this section.

(8) *Complaint Resolution Officials (CROs).* The employees you designate as CROs, for purposes of § 382.151 of this part, must receive training concerning the requirements of this part and the duties of a CRO prior to assuming their duties and at least once every twelve months thereafter.

(b) If you are a carrier that operates only aircraft with fewer than 19 passenger seats, you must ensure that your employees and contractors who directly interact with the traveling public are trained, as appropriate to their duties, to ensure that they are familiar with the matters listed in paragraph (a)(1) of this section, as well as to ensure they are knowledgeable on how to communicate with individuals with differing disabilities, how to physically assist individuals with mobility impairments, and how to properly handle passengers' wheelchairs and other assistive devices.

Issued this 27th day of February, 2024, in Washington, DC.

Peter Paul Montgomery Buttigieg,

Secretary.

[FR Doc. 2024–04729 Filed 3–11–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2024–C–1085]

Filing of Color Additive Petition From Phytolon Ltd.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Phytolon Ltd., proposing that the color additive regulations be amended to provide for the safe use of beetroot red for the coloring of foods generally in amounts consistent with current good manufacturing practice.

DATES: The color additive petition was filed on November 22, 2023.

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 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.

FOR FURTHER INFORMATION CONTACT: Christopher Kampmeyer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1255.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 4C0326), submitted by Phytolon Ltd., Ha-Tsmikha St, Yokne'am Illit, Israel. The petition proposes to amend the color additive regulations in part 73 (21 CFR part 73), ''Listing of Color Additives Exempt From Certification,'' to provide for the safe use of beetroot red for the coloring of foods generally in amounts consistent with current good manufacturing practice.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r), which applies to an action for substances which occur naturally in the environment, and for which the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05216 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 635

[Docket No. FHWA–2023–0037]

RIN 2125–AG13

Buy America Requirements for Manufactured Products

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The FHWA is proposing to discontinue its general waiver of Buy America requirements for manufactured products and in doing so require FHWA recipients to start applying Buy America requirements to manufactured products. The FHWA is also proposing standards for applying Buy America to manufactured products should the waiver be discontinued. The proposed standards for applying Buy America to manufactured products are consistent with the Office of Management and Budget's (OMB) guidance implementing the Build America, Buy America Act (BABA) provisions of the Infrastructure Investment and Jobs Act (also known as the Bipartisan Infrastructure Law (BIL)).

DATES: Comments must be received on or before May 13, 2024.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit comments by only one of the following means:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

All submissions should include the agency name and the docket number that appears in the heading of this document or the Regulation Identifier Number (RIN) for the rulemaking. All comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: For questions about this document, please contact Mr. Brian Hogge, Office of Infrastructure, (202) 366–1562, or via email at *brian.hogge@dot.gov.* For legal questions, please contact Mr. David Serody, Office of the Chief Counsel, (202) 366–4241, or via email at *david.serody@dot.gov.* Office hours are from 8 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are also available at *www.regulations.gov.* An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.FederalRegister.gov* and the U.S. Government Publishing Office's website at *www.GovInfo.gov.*

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late comments, FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date and interested persons should continue to examine the docket for new material. A final rule may be published at any time

after the close of the comment period and after FHWA has had the opportunity to review the comments submitted.

I. Executive Summary

A. Purpose of the Regulatory Action

The FHWA is required, by statute, to ensure that all FHWA-funded projects only use steel, iron, and manufactured products that are produced in the United States. 23 U.S.C. 313. The FHWA refers to these requirements as ''Buy America'' requirements. The Buy America requirement for manufactured products has existed in some form since the enactment of the 1978 Surface Transportation Assistance Act (1978 STAA), Public Law 95–599 (1978), with those requirements being modified by the 1983 Surface Transportation Assistance Act (1983 STAA), Public Law 97–424 (1983),[1] which provides the current Buy America requirement for manufactured products. In 1983, following the passage of the 1983 STAA, FHWA determined that it would be in the public interest to waive the Buy America requirements for manufactured products, creating the Manufactured Products General Waiver that continues to this day. *See* 48 FR 1946 (Jan. 17, 1983); 48 FR 53099 (Nov. 25, 1983). Due to the Manufactured Products General Waiver, manufactured products permanently incorporated into FHWA-funded projects do not need to be produced domestically, apart from predominantly iron or steel manufactured products and predominantly iron or steel components of manufactured products.

On November 15, 2021, the President signed BIL (Pub. L. 117–58) into law. The BIL includes the Buy America, Build America Act (BABA), which expands the coverage and application of Buy America requirements in Federal financial assistance programs for infrastructure. BIL, div. G sections 70901–70953. Among other requirements, BABA mandates that all iron, steel, manufactured products, and construction materials used in projects supported by funds made available for a Federal financial assistance program for infrastructure be produced in the United States. BABA section 70914. BABA provides that this mandate applies to such materials only to the extent that a domestic content procurement preference that meets the requirements of section 70914 does not already apply. BABA section 70917(a). As FHWA has an existing statutory Buy America requirement for steel, iron, and manufactured products at 23 U.S.C. 313, BABA's savings provision means that FHWA's existing Buy America requirements under 23 U.S.C. 313 apply to these products. The BABA's savings provision, however, requires that any domestic content procurement preference at least meets the requirements of section 70914. The requirements of section 70914 apply the definitions contained in section 70912, including the definition of ''produced in the United States.'' Accordingly, while FHWA does not directly apply BABA's manufactured products requirements, FHWA interprets BABA as requiring FHWA's Buy America requirements to be generally consistent with the BABA requirements that are applicable to section 70914, including the BABA definition of ''produced in the United States'' for manufactured products at section 70912(6)(B).

BABA also expresses a general policy preference against general applicability waivers like the Manufactured Products General Waiver. Section 70914(d) of BABA requires Federal Agencies to review existing general applicability waivers of Buy America requirements by publishing in the **Federal Register** a notice that: (i) describes the justification for the general applicability waiver; and (ii) requests public comments for a period of not less than 30 days on the continued need for the general applicability waiver. As described in further detail below, FHWA has undergone that review.

Based on the contents of that review, and after considering the President's policy, as embodied in Executive Order (E.O.) 14005, ''Ensuring the Future Is Made in All of America by All of America's Workers,'' to maximize the use of goods, products, and materials produced in the United States; the intent of Congress, as expressed in BABA's preference against general applicability waivers; the purpose and goals of domestic content procurement preferences and waivers; and FHWA's original rationale for issuing the Manufactured Products General Waiver compared to the current domestic manufacturing situation, FHWA is proposing the discontinuation of the Manufactured Products General Waiver. Simultaneously, FHWA is proposing to modify its current regulations implementing Buy America at 23 CFR 635.410 to set forth the standards for when a manufactured product will be considered to be ''produced in the United States'' and therefore Buy America-compliant. For uniformity and consistency with BABA, FHWA is proposing that these standards mirror the standards OMB has established for BABA's domestic content procurement preference for manufactured products in its final guidance implementing BABA at 2 CFR part 184 (part 184).[2] 88 FR 57750.

B. Summary of the Major Provisions of the Regulatory Action in Question

The FHWA is proposing to set standards regarding its Buy America requirement for manufactured products, defining when a manufactured product is ''produced in the United States'' for the purposes of complying with 23 U.S.C. 313. Under this definition, which mirrors the definition at section 70912(6)(B) of BABA and in part 184, to be produced in the United States, a manufactured product must be manufactured in the United States and have the cost of components of the product that are mined, produced, or manufactured in the United States be greater than 55 percent of the total cost of all components of the manufactured product. The FHWA is also proposing to mirror the standard in part 184 for how to determine the cost of any component. To provide clarity in presenting these standards, FHWA is also proposing to define ''component,'' ''manufactured product,'' and ''manufacturer,'' with these definitions again proposed to be substantially similar to those used in part 184.

In addition, FHWA is not proposing to modify its current Buy America requirements for iron and steel.[3] To distinguish between iron and steel products, to which FHWA's existing Buy America requirements will continue to apply, and manufactured products, FHWA is proposing to adopt the definitions of ''iron or steel products'' and ''predominantly of iron or steel or a combination of both'' found in part 184.

In alignment with part 184, FHWA is also establishing a separate classification for excluded materials,

[1] For clarity, while this law was enacted as the Surface Transportation Assistance Act of 1982, because it was enacted on January 6, 1983, it will be referred to as the ''1983 STAA.''

[2] Throughout this document, references to part 184 refer to both the text in 2 CFR part 184 and the Preamble published in the **Federal Register**.

[3] The FHWA's longstanding Buy America requirements for iron and steel require that all manufacturing processes of permanently incorporated steel or iron materials, including application of a coating, must occur in the United States. 23 CFR 635.410(b)(1). BABA included domestic content procurement preferences for iron and steel at section 70912(2)(A), which require that all manufacturing processes, from the initial melting stage through the application of a coating, occur in the United States. Since FHWA's requirements for iron and steel meet BABA's requirements for iron and steel, FHWA continues to apply its existing Buy America requirements unchanged. The FHWA notes, however, that its current Buy America requirements for iron and steel are substantially aligned with BABA's.

referred to as section 70917(c) materials in part 184. These excluded materials are cement and cementitious materials; aggregates such as stone, sand, or gravel; or aggregate binding agents or additives. The FHWA is proposing to make clear that, standing alone, these excluded materials do not constitute a manufactured product for which a Buy America requirement applies. Under FHWA's proposed regulations, such excluded materials may constitute a component of a manufactured product when combined with other materials, including other excluded materials; however, FHWA is proposing to explicitly state that concrete and asphalt mixtures delivered to a job site without final form for incorporation into a project are not manufactured products.

In addition, for clarity, FHWA is proposing to make clear that a product must either be classified as an iron or steel product, a manufactured product, an excluded material, or another category specified by law or in 2 CFR part 184, such as construction materials. The FHWA believes that this, in concert with the new definitions, will make clear how recipients of FHWA financial assistance should differentiate between different materials and ensure that multiple standards do not apply to a single material, with exceptions for two specific manufactured products described below.

The FHWA proposes to deviate from the part 184 by applying FHWA's existing Buy America requirements for iron and steel to two specific types of materials that may be used as components of manufactured products, with those manufactured products also required to conform with FHWA's proposed Buy America requirements for manufactured products.[4] First, with respect to precast concrete products that are classified as manufactured products, FHWA is proposing to require that any iron or steel products that are components of the precast concrete product must conform with FHWA's existing Buy America requirements for iron and steel. Second, with respect to intelligent transportation systems and other electronic hardware systems that are installed in the highway right-of-way or other real property and classified as manufactured products, FHWA is proposing to require that any iron or steel enclosures of such systems conform with FHWA's existing Buy America requirements for steel and iron. The FHWA is proposing these two deviations from part 184 in order to continue FHWA's long-standing policy of requiring the iron or steel in these specified products to comply with the Buy America requirements for iron and steel, while also limiting the number of products that must comply with two different Buy America requirements. Along with these iron and steel requirements, under FHWA's proposed standards, precast concrete and such electronic hardware systems, when classified as manufactured products, would still need to meet FHWA's proposed standards for manufactured products; therefore, the cost of the iron and steel within the products shall count toward the 55 percent domestic content threshold.

C. Benefits and Costs

The preliminary regulatory impact analysis (RIA) prepared pursuant to Executive Order 12866, ''Regulatory Planning and Review,'' and available in the rulemaking docket, analyzes the costs and benefits associated with establishing Buy America requirements for manufactured products. The RIA discusses anticipated benefits of the rule qualitatively, as they could not be quantified. Expected benefits include protecting and expanding domestic manufacturing, increasing supply chain resiliency, and increasing consistency in applying domestic content procurement preferences for manufactured products between FHWA and other Federal Agencies that are subject to the requirements of BABA. Expected costs of the proposed rule relate to increased material costs for manufactured products used in highway construction projects, project delay, and the administrative costs to FHWA and recipients of FHWA financial assistance. At this time, FHWA is only able to quantify costs for the increased material costs and the administrative costs to FHWA. The FHWA estimates the increased material costs for manufactured products permanently incorporated into FHWA-funded projects to range from a high of roughly $737 million per year to a low of $45 million per year. The FHWA further estimates an additional $167,000 per year in increased FHWA administrative costs. The other administrative costs to recipients of FHWA financial assistance and the costs associated with project delivery delay have not been quantified.

II. Background

A. History of FHWA's Manufactured Products Domestic Content Procurement Preference and Manufactured Products General Waiver

The FHWA's Buy America requirements for the Federal-aid highway program were first established in 1978 by Section 401 of the 1978 STAA, which imposed a Buy America requirement to certain unmanufactured and manufactured articles, materials, and supplies. Following enactment of the 1978 STAA, FHWA issued an emergency rule to implement the Buy America requirement of Section 401. *See* 43 FR 53717 (Nov. 17, 1978). In that rule, FHWA determined that it was in the public interest to temporarily waive the provisions of Section 401 of the 1978 STAA to all products and materials other than structural steel. 43 FR at 53717. The FHWA based this determination on its belief that the implementation of the statutory text of Section 401 would have a major impact on the Federal-aid highway program and that foreign structural steel was the only foreign product with a significant nationwide effect on the cost of Federal-aid highway construction projects. *Id.*

In 1980, following this emergency rule, FHWA issued an NPRM to establish regulations implementing Section 401 of the 1978 STAA. 45 FR 77455 (Nov. 24, 1980). In that NPRM, FHWA proposed to extend the coverage of Buy America requirements to all steel construction materials used in highway construction projects, while excluding all other materials and products from coverage under Section 401. 45 FR at 77455. Again, FHWA stated that because foreign steel was identified as the only foreign commodity having a significant nationwide effect on the cost of Federal-aid highway construction projects, it was only necessary to implement Buy America requirements for steel products. *Id.* The FHWA acknowledged that natural materials, such as sand, stone, gravel, and earth materials; and petroleum and petroleum-based products, such as fuels, lubricants, and bituminous products, were two other commodities used in large amounts for Federal-aid highway projects, but FHWA proposed not to apply Buy America requirements to such materials. *Id.* The FHWA found that there was limited foreign competition in natural materials because of the difficulty and high cost of transporting them due to their bulk and weight; as these materials were therefore usually domestically sourced, FHWA found it unnecessary to apply Buy America requirements to them. *Id.*

[4] Unlike these proposed regulations, under part 184, materials should not be considered to fall into multiple categories, and only need to meet the domestic content procurement preference for only the single category in which it is classified. *See* 2 CFR 184.4(e), (f).

For petroleum and petroleum-based products, FHWA determined that such products were not available from domestic sources in sufficient and reasonably available quantities, justifying their exemption from FHWA's proposed Buy America requirements. *Id.* For all other manufactured products covered by Section 401 of the 1978 STAA, FHWA determined that they were not used in sufficient quantity to have any appreciable effect on the overall cost of a project and did not require the protection of Buy America. The FHWA therefore proposed in the 1980 NPRM not to apply Buy America requirements to such products.

Prior to this rulemaking being finalized, Congress enacted the 1983 STAA, which repealed Section 401 of the 1978 STAA and instituted new Buy America requirements that are similar to those that exist today. Section 165(a) applied Buy America requirements to all steel, cement, and manufactured products used on FHWA-funded projects.[5] Subsection 165(b) provided that FHWA could waive the provisions of subsection 165(a) if their application would be inconsistent with the public interest; if such materials and products are not produced in the United States in sufficient and reasonable quantities and of a satisfactory quality; or if the inclusion of domestic material(s) would increase the cost of the overall project by more than 25 percent.[6]

Shortly after the enactment of the 1983 STAA, FHWA issued an interim final rule implementing Section 165. 48 FR 1946 (Jan. 17, 1983). In this rule, FHWA again determined that it was in the public interest to temporarily waive the provisions of Section 165 of the 1983 STAA as they applied to all manufactured products other than cement. 48 FR at 1946. The FHWA based this decision ''on the fact that sufficient information is not yet available in order to adequately assess the impacts of applying Buy America provisions to all manufactured products and to all projects regardless of project cost.'' *Id.* The FHWA also noted that applying a Buy America requirement for all manufactured products would require tracing the origin of components used in petroleum-based products, which FHWA stated was extremely difficult to do. *Id.*

In late 1983, FHWA issued its final rule implementing Section 165 of the 1983 STAA, creating its current Buy America regulations at 23 CFR 635.410. 48 FR 53099 (Nov. 25, 1983). Once more, FHWA found that a waiver of Buy America requirements for manufactured products was in the public interest, thereby creating the Manufactured Products General Waiver, which still remains in effect 40 years later.[7] 48 FR at 53102. The FHWA found that most responses from product manufacturers ''recommended that manufactured products should be excluded from Buy America and/or expressed only a passing interest in the regulation.'' 48 FR at 53101. For manufacturers that wanted Buy America requirements applied to manufactured products, FHWA stated that these manufacturers primarily expressed this opinion because they opposed unfair foreign trade practices, and that ''protectionism in terms of a Buy America regulation on all manufactured products would not serve this purpose.'' *Id.* Rather than apply Buy America requirements for manufactured products to remedy this concern, FHWA stated that unfair practices could be instead addressed through import laws. *Id.* at 53102. Further, FHWA determined that it was not the intent of Congress in enacting the 1983 STAA for FHWA to apply a Buy America requirement to manufactured products; FHWA noted that it had consistently waived manufactured products from coverage under Buy America laws and Congress did not specifically direct a change in that policy in enacting 1983 STAA, which FHWA interpreted to mean that not all manufactured products had to be covered by the requirements of Section 165. *Id.* at 53101–02. Finally, FHWA reiterated that materials and products other than steel, cement, asphalt, and natural materials comprised a small percent of the highway construction program; that other manufactured products were minimally used and there would be little economic effect to applying Buy America requirements to them; and that it would be difficult and administratively burdensome to identify the various materials comprising manufactured products and trace their origin. *Id.* at 53102.

B. Current FHWA Buy America Requirements Under 23 U.S.C. 313

Currently, 23 U.S.C. 313(a) requires that all steel, iron, and manufactured products used in FHWA-funded projects be produced in the United States. Per 23 U.S.C. 313(h), these Buy America requirements apply to all contracts that are eligible for FHWA assistance regardless of the funding source if any contract within the scope of a determination under the National Environmental Policy Act (NEPA) involves an obligation of Federal funds. For purposes of section 70917 of BABA, FHWA considers 23 U.S.C. 313 to be a domestic content procurement preference in existence at the time of the enactment of BIL meeting the requirements of section 70914 with respect to iron, steel and manufactured products for all financial assistance that is administered under title 23, U.S.C.[8] However, as noted above in Section II.A, in 1983, FHWA issued a public interest waiver of general applicability of FHWA's Buy America requirement for manufactured products, known as the Manufactured Products General Waiver. Thus, were FHWA to discontinue this waiver, FHWA would need to establish standards for the application of Buy America to manufactured products that meet or exceed the requirements of section 70914. Accordingly, FHWA is publishing this NPRM to propose such standards.

[5] The Buy America requirement for cement was eliminated by Congress in 1984. *See* Public Law 98–229. In addition, Congress added a Buy America requirement for iron in 1991. *See* Public Law 102–240. The FHWA's current Buy America requirements for steel, iron, and manufactured products were codified at 23 U.S.C. 313 by Section 1903 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) in 2005. Public Law 109–59.

[6] Section 165(b)(3) of the 1983 STAA also allowed for a waiver of the provisions in subsection 165(a) in the case of the procurement of bus and other rolling stock under the Urban Mass Transportation Act of 1964 if the cost of components which are produced in the United States is more than 50 percent of the cost of all components of the vehicle or equipment; and final assembly of the vehicle or equipment has taken place in the United States. This use of components is referenced in subsection 165(c) of the 1983 STAA, which states that for the purposes of Section 165, in calculating components' costs, labor costs involved in final assembly cannot be included. Subsection 165(c) was modified by Section 337 of the Surface Transportation and Uniform Relocation Assistance Act of 1987 (Pub. L. 110–17), raising the threshold for the cost of components. In addition, Section 337(b) of the Surface Transportation and Uniform Relocation Assistance Act of 1987 amended Section 165(b)(3) of the 1983 STAA to refer to the cost of all subcomponents, as well as components. Section 165(b)(3) was ultimately repealed by Section 4(r) of Public Law 103–272 in 1994; however, subsection 165(c) of the 1983 STAA remains codified at 23 U.S.C. 313(c).

[7] The FHWA's regulations implementing Buy America have also remained consistent since 1983, apart from reacting to statutory changes by removing a reference to a Buy America requirement for cement (49 FR 18820 (May 3, 1984)) when Congress removed that Buy America requirement and adding a reference to a Buy America requirement for iron (58 FR 38973 (July 21, 1993)) after Congress added that requirement.

[8] Financial assistance made available for Federal Lands Management Agencies under the Federal Lands Transportation Program is subject to the Buy American Act provision (41 U.S.C. 8301–8303) under the Federal Acquisition Regulations. Throughout this document, FHWA refers to the projects subject to FHWA's Buy America requirements as ''FHWA-funded projects.''

C. Administration Priorities

In January 2021, President Biden issued E.O. 14005, titled ''Ensuring the Future is Made in All of America by All of America's Workers'' (86 FR 7475, Jan. 28, 2021). The E.O. sets forth a policy that Federal Agencies should, consistent with applicable law, maximize the use of goods, products, and materials produced in, and services offered in, the United States. The E.O. helps promote private sector investment in the production of goods critical to our national security and economic stability. It is a policy of this Administration, exemplified by this E.O., to bolster domestic supply chains and, in doing so, create jobs, strengthen our manufacturing sector, and create economic opportunities for more of America's small businesses. Indeed, President Biden emphasized the importance of using domestic products in American roads, bridges, and highways in his 2023 State of the Union Address.[9]

D. Build America, Buy America Act

On November 15, 2021, the President signed into law BIL, which includes BABA. The BABA requires that all iron, steel, manufactured products, and construction materials made available for a Federal financial assistance program for infrastructure be produced in the United States. BABA section 70914. The BABA, however, provides that the preferences under section 70914 apply only to the extent that a domestic content procurement preference as described in section 70914 does not already apply to iron, steel, manufactured products, and construction materials. BABA section 70917(a)–(b). As FHWA has existing Buy America domestic content preferences for steel, iron, and manufactured products at 23 U.S.C. 313, BABA's preferences for those materials do not explicitly apply to FHWA. The FHWA does, however, apply BABA's domestic preference requirement for construction materials.[10]

Under BABA, all manufactured products must be ''produced in the United States.'' BABA section 70914. With respect to manufactured products, BABA defines ''produced in the United States'' to mean that (1) the manufactured product was manufactured in the United States and (2) the cost of the components of the manufactured product that are mined, produced, or manufactured in the United States is greater than 55 percent of the total cost of all components of the manufactured product, unless another standard for determining the minimum amount of domestic content of the manufactured product has been established under applicable law or regulation. BABA section 70912(6)(B).

In addition, BABA expresses a general policy preference against general applicability waivers, such as the Manufactured Products General Waiver. For example, section 70913(c) of BABA requires Federal Agencies to identify ''deficient programs'' for financial assistance, which includes programs that are ''subject to a waiver of general applicability not limited to the use of specific products for use in a specific project.'' BABA section 70913(c)(2). Section 70914(d) of BABA also requires Federal Agencies to review existing general applicability waivers of Buy America requirements by publishing in the **Federal Register** a document that: (i) describes the justification for the general applicability waiver; and (ii) requests public comments for a period of not less than 30 days on the continued need for the general applicability waiver. Following the initial notice and review and consideration of comments received, BABA requires Federal agencies to publish in the **Federal Register** a determination on whether to continue or discontinue the general applicability waiver. BABA section 70914(d)(2)(B). On March 17, 2023, at 88 FR 16517, FHWA published the required notice to initiate its review of the Manufactured Products General Waiver in the **Federal Register** (''2023 RFC''). The FHWA discusses the comments received for the 2023 RFC in section III.

E. OMB's Guidance on BABA

The BABA further required OMB to issue guidance to assist in applying BABA's requirements. BABA section 70915. On April 18, 2022, OMB issued memorandum M–22–11, ''Initial Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure,'' [11] which was rescinded and replaced by memorandum M–24–02, ''Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure'' on October 25, 2023 (''Implementation Guidance'').[12] Section VI of the Implementation Guidance warns against overly broad waivers, stating that they ''undermine market signals designed to boost domestic supply chains, particularly for key articles, materials, and supplies in critical supply chains,'' and that ''[w]aivers that are overly broad will tend to undermine domestic preference policies.'' Section VI also states that public interest waivers of domestic content procurement preferences ''must be used judiciously and construed to ensure the maximum utilization of goods, products, and materials produced in the United States.'' The Implementation Guidance goes on to state that whether a waiver is in the public interest will depend upon numerous factors, such as the nature and amount of resources available to the recipient; the value of the items, goods, or materials in question; the potential domestic job impacts; and other policy considerations, including sustainability, equity, accessibility, performance standards, and the domestic content (if any) of and conditions under which the non-qualifying good was produced. In terms of general applicability waivers, section VI of the Implementation Guidance states that Agencies ''should align such waivers with complementary policies, such as work to boost supply chain resiliency and domestic employment'' and that such waivers ''should include appropriate expiration dates designed to ensure that, once available, Buy America qualifying products receive appropriate consideration.''

On August 23, 2023, at 88 FR 57750, OMB revised its guidance in title 2 of the CFR to add a new part 184 that provides additional guidance on implementing BABA. Part 184 includes definitions for key terms, including iron or steel products, predominantly of iron or steel or a combination of both, manufactured products, component, and manufacturer. 2 CFR 184.3. In line with section 70912(6)(B) of BABA, 2 CFR 184.3 states that a manufactured product is ''produced in the United

[9] As stated by President Biden: ''And on my watch, American roads, bridges, and American highways are going to be made with American products as well.'' *See https://www.whitehouse.gov/state-of-the-union-2023/.*

[10] Along with applying BABA's domestic preference requirement for construction materials, section 70916(c) of BABA requires FHWA to consult with the Director of the Hollings Manufacturing Extension Partnership regarding whether there is a domestic entity that could provide the iron, steel, manufactured product, or construction material that is the subject of the proposed waiver before FHWA grants a waiver under either its Buy America requirements for iron, steel, and manufactured products and under BABA's domestic preference requirement for construction materials.

[11] *https://www.whitehouse.gov/wp-content/uploads/2022/04/M-22-11.pdf.*

[12] *https://www.whitehouse.gov/wp-content/uploads/2023/10/M-24-02-Buy-America-Implementation-Guidance-Update.pdf.*

States'' if the product was manufactured in the United States; and the cost of the components of the manufactured product that are mined, produced, or manufactured in the United States is greater than 55 percent of the total cost of all components of the manufactured product, unless another standard that meets or exceeds this standard has been established under applicable law or regulation for determining the minimum amount of domestic content of the manufactured product. Part 184 also provides guidance for determining the cost of components of manufactured products. Pursuant to 2 CFR 184.5, in determining whether the cost of components for manufactured products is greater than 55 percent of the total cost of all components, there are two standards depending on the origin of the component. For components purchased by the manufacturer, the cost of the component is the acquisition cost, including transportation costs to the place of incorporation into the manufactured product (whether or not such costs are paid to a domestic firm), and any applicable duty (whether or not a duty-free entry certificate is issued). 2 CFR 184.5(a). For components manufactured by the manufacturer, the cost of the component is all costs associated with the manufacture of the component, including transportation costs described in 2 CFR 184.5(a), plus allocable overhead costs, but excluding profit and any costs associated with the manufacture of the manufactured product. 2 CFR 184.5(b).

Part 184 also states that an article, material, or supply should only be classified as either an iron or steel product, manufactured product, construction material, or section 70917(c) material,[13] that the classification must be made based on the status of the material at the time it is brought to the work site for incorporation into an infrastructure project, and that the material must meet the Buy America standards for only the single category in which it is classified. 2 CFR 184.4(e)–(f).

Again, part 184 does not, by its own terms, apply to FHWA's Buy America requirements for steel, iron, and manufactured products; it only applies to FHWA's domestic content procurement preference for construction materials.[14] 2 CFR 184.2(a). Part 184 does, however, apply to all Federal financial assistance programs for infrastructure that are administered by Federal Agencies that did not have a domestic content procurement preference for steel, iron, and manufactured products meeting or exceeding BABA's requirements.

III. March 17, 2023, Request for Comments

A. Overview of Comments Received

Pursuant to section 70914(d) of BABA, FHWA published the March 17, 2023, Request for Comments (RFC), seeking comments on whether to continue or discontinue the Manufactured Products General Waiver. 88 FR 16517. The FHWA received 9,496 comments; however, a vast majority of these comments received were ''form'' comments that were functionally identical to each other, with only occasional minor changes to the comments themselves under the names of different commenters. The majority of these form comments expressed support for discontinuing the Manufactured Products General Waiver, although there were also form comments that supported continuing the waiver. While FHWA believes that form comments might broadly indicate the level of support or opposition to the waiver, no form comment provided substantive analysis regarding the benefits or costs of continuing or discontinuing the Manufactured Products General Waiver.

Excluding the form comments, FHWA received 134 unique, substantive comments from State departments of transportation, manufacturers, State government agencies, labor organizations, construction contractors, industry associations, members of Congress, and individuals. The FHWA briefly discusses the main topics brought up by commenters who supported and opposed the Manufactured Products General Waiver below.

B. Comments in Favor of Continuing the Manufactured Products General Waiver

Commenters who were in favor of continuing the Manufactured Products General Waiver generally presented similar points. Such commenters stated that removing the waiver (1) would likely increase project costs due to the increased cost of domestically produced products or due to the reduced size of the market for Buy America-compliant products; (2) would likely lead to project delays or cancellations due to the difficulty or inability to acquire Buy America-compliant products, partly due to a limited supply of such products; (3) may prevent the use of specific products because some products or their components not currently produced domestically and onshoring will take time, if it occurs at all, given the size of the market for Buy America-compliant products and components; and (4) would result in significant challenges if contracting agencies, contractors, and manufacturers were required to track the origin of a product's components, which commenters claimed would be worsened if these entities also had to track the cost of a product's components. Many commenters argued that these issues were particularly pronounced and any benefits of rescinding the Manufactured Products General Waiver would be limited given their assertions that the cost and amount of manufactured products used in highway construction projects are insignificant relative to the rest of the materials used in highway construction projects.

Commenters acknowledged that, were FHWA to rescind the Manufactured Products General Waiver and apply Buy America requirements for manufactured products, a waiver could be obtained for manufactured products that are not available from domestic sources; however, commenters argued that going through the waiver process would inevitably take time and therefore slow construction down, add administrative burden, and may result in duplicative waivers continually being requested for the same product that is included in multiple projects.

C. Comments in Favor of Discontinuing the Waiver

Comments in favor of discontinuing the waiver and applying Buy America requirements on manufactured products generally espoused the belief that doing so would restore America's manufacturing base, create and protect American jobs, and stimulate domestic economic growth. Commenters also noted that recent supply chain disruptions indicate the benefit of producing products in the United States and minimizing dependence on foreign sources, which these commenters argued also supports America's national security. Commenters who favored discontinuing the Manufactured Products General Waiver, in general, stated their belief that when taxpayer dollars are spent on federally financed

[13] Part 184 defines a section 70917(c) material as cement and cementitious materials; aggregates such as stone, sand, or gravel; or aggregate binding agents or additives. *See* 2 CFR 184.3. These materials are named section 70917(c) materials in part 184 because they are referred to in section 70917(c) of BABA.

[14] Since 23 U.S.C. 313 did not specifically apply to ''construction materials,'' FHWA did not have a domestic content procurement preference in effect for these products for purposes of section 70917 of BABA. Therefore, the provisions of BABA as interpreted by OMB apply to construction materials.

infrastructure projects, those dollars should go to domestically produced products.

Commenters also argued that rescinding the Manufactured Products General Waiver would provide an incentive for companies to invest in U.S. manufacturing, which they argued the current Manufactured Products General Waiver disincentivizes. Commenters noted that switching from foreign-produced products to domestically produced products would reward companies that have moved production onshore, hired American workers, and conducted their operations in compliance with strong U.S. environmental and worker safety regulations. As one commenter stated, each time FHWA employs the Manufactured Products General Waiver, it fails to account for whether a Buy America requirement for manufactured products was feasible, let alone probable. Another commenter stated that strong domestic content standards send demand signals for companies to invest in domestic production and workers. In a similar vein, commenters argued that the continued existence of the waiver eliminates any incentive for future domestic investment for manufactured products used on FHWA-funded projects. Commenters also pointed out that companies that wish to make manufactured products for FHWA-funded projects domestically do not receive any protection under the Manufactured Products General Waiver and must instead compete with foreign imports. Commenters further noted that the Manufactured Products General Waiver encourages the use of cheaper foreign-produced manufactured products on FHWA-funded projects and denies opportunities for U.S. manufacturing workers.

Despite these issues, some manufacturers and contracting agencies also indicated that they intend to increase domestic manufacturing capacity in response to the increased Federal transportation investments brought about by BIL, which indicates that there may be expansion capabilities for manufacturers who wish to produce Buy America-compliant manufactured products. Other manufacturers commented that they believed they were able to produce a Buy America-compliant product and therefore desired the rescission of the current waiver to take advantage of the market for Buy America-compliant products. These manufacturers stated that because of the Manufactured Products General Waiver, they must compete with foreign manufacturers who may seek to undermine their pricing, have their products subsidized by foreign governments, or dump their products into the U.S. market.

In addition, commenters stated their belief that the Manufactured Products General Waiver was an inappropriate use of FHWA's waiver authority when it was issued in 1983, arguing that the 1983 STAA clearly directed and intended that FHWA require the use of U.S.-produced manufactured products in FHWA-funded projects.

Commenters also stated that the Manufactured Products General Waiver is inconsistent with the intent of Congress, as seen through the enactment of BIL. These commenters pointed to the fact that, where it applies, section 70914 of BIL requires the head of each Federal Agency to ensure that none of the funds available for a Federal financial assistance program for infrastructure may be obligated unless all of the manufactured products used in the project are produced in the United States; section 70913(c) of BIL defines programs for which a domestic content procurement preference requirement is subject to a waiver of general applicability not limited to the use of specific products for use in a specific project, like the Manufactured Products General Waiver, as ''deficient programs;'' and that section 70914(d) of BIL requires Federal Agencies to review existing waivers of general applicability and determine whether to continue or discontinue them.

IV. Proposed Discontinuation of the Manufactured Products General Waiver

The FHWA has carefully considered comments received on the 2023 RFC, the purpose of its Buy America requirements, the rationale provided by FHWA in issuing the Manufactured Products General Waiver in 1983, the priorities of the Administration, and the goal of Congress in enacting the domestic content procurement preferences in BABA, in determining whether the Manufactured Products General Waiver remains in the public interest. After considering this information, FHWA has decided to propose to discontinue the manufactured products waiver.

First, both the intent of Congress, as expressed in secs. 70933 and 70935 of BABA, and the President's policy for the Federal Government, as expressed in section 1 of E.O. 14005, is that Federal Agencies should use terms and conditions in Federal financial assistance awards to maximize the use of goods, products, and materials produced in the United States. Continuing the long-standing Manufactured Products General Waiver is not consistent with these policy goals.

Second, FHWA believes it is important to recognize the purpose of domestic content procurement preferences when considering whether a waiver is applicable and in the public interest. The Congressional findings in section 70911 of BABA are instructive regarding the purposes of domestic content procurement preferences. In general, the findings provide that taxpayers expect that publicly funded infrastructure will be produced in the United States by American workers, applying America's high environmental, worker, and workplace safety standards; that taxpayer dollars should not reward companies that have moved their operations and jobs to foreign countries; that publicly funded infrastructure projects should seek to prevent shifts in manufacturing to foreign countries, who may use less energy efficient and more polluting manufacturing methods, from the United States; that such projects should create a demand for domestically produced goods, helping to sustain and grow domestic manufacturing and the jobs domestic manufacturing supports throughout product supply chains; and that taxpayer funding should sustain a robust domestic manufacturing sector, which is a vital component of the national security of the United States. *See* BABA section 70911. Continuing the long-standing Manufactured Products General Waiver continues to undermine the expressed purposes that domestic content procurement preferences, such as FHWA's Buy America requirement, are intended to serve.

Third, OMB's Implementation Guidance conveys a policy that waivers, including waivers of general applicability like the Manufactured Products General Waiver, should not be overly broad in order to ensure that any such waivers appropriately convey market signals on where the domestic supply chain can be bolstered for American manufacturers to take advantage of. The Implementation Guidance further provides that such waivers should also be time-limited to ensure that, once available, Buy America-compliant materials can receive appropriate consideration for inclusion in federally funded projects. The Manufactured Products General Waiver is inconsistent with these general principles.

Taking into account these above references, FHWA believes the Manufactured Products General Waiver is overly broad. The FHWA has considered comments stating that manufactured products that can be

manufactured domestically are more likely to be ignored in favor of cheaper foreign products for use on FHWA-funded projects. The FHWA agrees with these commenters that the Manufactured Products General Waiver disincentivizes manufacturers from domestically producing products by covering all manufactured products without discretion, rather than specifically targeting those that would warrant a waiver under the waiver criteria in 23 U.S.C. 313(b). Further, FHWA believes the broadness of the Manufactured Products General Waiver can be seen in the fact that it applies to any newly created manufactured product without an analysis of whether coverage of that product is in the public interest.

The Manufactured Products General Waiver also fails to provide domestic manufacturers who wish to produce products for FHWA-funded projects with knowledge of the current gaps in the domestic manufacturing sector. By covering all manufactured products, the Manufactured Products General Waiver does not provide market signals that distinguish between manufactured products that are made domestically but not included in FHWA-funded projects because the products are more expensive than foreign products and manufactured products that are not produced domestically at all. This lack of clarity hinders manufacturers who wish to enter the market from understanding the competitive landscape, disincentivizing them from attempting to provide domestic manufactured products for FHWA-funded projects.

The FHWA believes it is important to compare its current understanding of the purpose and need for waivers with the fundamental underpinnings of the Manufactured Products General Waiver when it was issued in 1983. At that time, FHWA stated that a waiver was necessary because of the costs of applying a Buy America requirement to manufactured products—primarily the burden in identifying and tracing the origin of the components of manufactured products—while those products comprised only a small percent of the highway construction program. 48 FR at 53102. While FHWA recognized these costs, FHWA did not seemingly perceive any benefits of a Buy America requirement for manufactured products because it believed that manufacturers would not produce Buy America-compliant products due to the limited demand created by FHWA-funded projects; such nonexistent products would thus not require Buy America protection. In other words, when issuing the Manufactured Products General Waiver, FHWA presumed at the time that domestic manufacturers would not produce Buy America-compliant products. The purpose of the waiver was thus to allow for the incorporation of products from foreign sources to fill what FHWA perceived would always be gaps in domestic manufacturing. It assumed that domestic manufacturing would not produce Buy America-compliant products and thus believed this assumption compelled the need for a broad waiver of general applicability.

The FHWA no longer agrees with this premise and is accordingly proposing to discontinue the Manufactured Products General Waiver. The FHWA notes that the Federal-aid highway program has grown considerably with the enactment of new funding programs that provide new eligibilities since the Manufactured Products General Waiver was established in 1983. As shown by commenters, domestic manufacturers are available to produce Buy America-compliant products used in Federal-aid highway funding programs. Keeping the Manufactured Products Waiver in place provides no incentive for new domestic manufacturers to enter the market or for existing domestic manufacturers to begin producing Buy America-compliant products. For nascent industries that produce manufactured products used in FHWA-funded projects, the Manufactured Products General Waiver also discourages companies from investing in domestic manufacturing that may be able to compete globally once the domestic manufacturers have built up expertise. Further, FHWA believes that due to the development of new kinds of manufactured products as well as the expansion of program eligibilities, such as the establishment of the Surface Transportation Block Grant Program and Congestion Mitigation and Air Quality Improvement Program, manufactured products as a category are used more often now than when the Manufactured Products General Waiver was issued and accordingly have a larger economic effect now. When issuing the waiver in 1983, FHWA stated that materials and products other than steel, cement, asphalt, and natural materials comprised a small percentage of the highway construction program. Commenters on the 2023 RFC, however, referenced numerous other products that they believed would be affected by rescission of the Manufactured Products General Waiver, such as ITS hardware, traffic signals and controllers, and vehicle detection equipment.

Unlike the Manufactured Products General Waiver, FHWA instead believes, in line with OMB's Implementation Guidance, that waivers should aim to proactively encourage domestic manufacturing by providing clear market signals about which markets domestic manufacturers can enter with the reasonable expectation that their products could adequately compete for use on FHWA-funded projects. The FHWA acknowledges that waivers may be necessary in some circumstances but believes that waivers should seek to identify areas where domestic manufacturing can fill gaps and actively encourage such activity.

Accordingly, FHWA believes that the Manufactured Products General Waiver is overly broad, no longer in line with the purpose of domestic content procurement preferences and waivers, and therefore no longer serves the public interest. The FHWA is thus proposing to discontinue the Manufactured Products General Waiver. In doing so, FHWA seeks to encourage manufacturers to supply Buy America-compliant products to FHWA-funded projects and to encourage other manufacturers to shift their production to the United States to take advantage of this market.

The FHWA believes that rescinding the Manufactured Products General Waiver will also provide many benefits to the United States, such as protecting and increasing domestic manufacturing and manufacturing jobs, providing an opportunity for manufacturing innovations to occur domestically, and creating a more resilient domestic supply chain and protecting national security. In addition, FHWA expects increases in domestic manufacturing to benefit related domestic industries, such as component manufacturers and material and product transporters.

At the same time, FHWA understands that discontinuing the Manufactured Products General Waiver and applying Buy America requirements on manufactured products may result in cost increases, project delays, and product unavailability if not done carefully. The FHWA acknowledges that there may be some products that are not currently produced in the United States and, for various reasons, might not be able to be produced in the United States in the near future. For such products, FHWA intends to consider whether it should propose any targeted waivers, with these waivers providing a timeline to encourage manufacturers to ramp up domestic production. To that end, FHWA is concurrently publishing a Request for Information (RFI), seeking specific and detailed information on

what products are not and cannot be produced in the United States in the near future. Based on information received, FHWA intends to propose time-limited and targeted waivers covering such products, if it determines it would be appropriate to do so. The FHWA believes that issuing targeted waivers for certain manufactured products presents a better model than the current Manufactured Products General Waiver, which does not consider the availability of individually manufactured products and has no set ending in order to incentivize the onshoring of manufacturing.

With the FHWA RFI, FHWA seeks to mitigate the concerns posed by commenters that rescinding the waiver will cause cost increases and project delays by ensuring the continued availability of necessary manufactured products. The FHWA would intend for such waivers to allow for the use of foreign manufactured products as domestic production ramps-up. Such waivers would be time-limited and could include an explicit schedule for phasing out a waiver over time, creating a glide-path toward full Buy America compliance for products, where possible. The FHWA's goal is that once these waivers expire, the domestic production of any covered product would be sufficient to ensure that Buy America-compliant products would be available for use in FHWA-funded projects. Such waivers could also take into account situations where economic realities, such as the size of the market, the cost of onshoring production, and geographic constraints (such as products made of materials that are not mined in the United States) may hinder domestic manufacturing growth even in the longer term, though such waivers would still be subject to periodic review.

By issuing waivers for products where necessary, FHWA intends to ensure that manufactured products needed for highway construction projects are available while also providing an advantage to domestic manufacturers who can provide manufactured products to FHWA-funded projects where a waiver is not needed. In addition, such targeted waivers afford manufacturers insight into market demand that can trigger capital investments in domestic manufacturing to fill current gaps in the Nation's supply chain, thereby decreasing the need for these waivers over the long-term. The FHWA will consider such waivers where they are deemed necessary to ensuring the availability of products at a reasonable price; however, where domestic production is currently feasible, FHWA believes in allowing Buy America requirements to operate as a useful incentive for domestic manufacturers to contribute American-made manufactured products to highway construction projects.

In addition, DOT has issued a ''Waiver of Buy America Requirements for De Minimis Costs and Small Grants'' (''De Minimis and Small Grants Waiver''). 88 FR 55817 (Aug. 16, 2023). The De Minimis and Small Grants Waiver currently has no operative effect on manufactured products included in FHWA-funded projects, as such products are covered by the Manufactured Products General Waiver. Were the Manufactured Products General Waiver to be rescinded, however, the De Minimis and Small Grants Waiver would waive the application of FHWA's Buy America requirements for manufactured products under a single financial assistance award for which (1) the total value of non-compliant products is no more than the lesser of $1,000,000 or 5 percent of total applicable costs for the project; or (2) the total amount of Federal financial assistance applied to the project, through awards or subawards, is below $500,000. 88 FR at 55820. For smaller projects and projects using limited amounts of manufactured products, where there is less of a benefit to discontinuing the Manufactured Products General Waiver, FHWA believes that the De Minimis and Small Grants waiver should prevent the rescission of the waiver from increasing project costs or causing project delays.

For all of the above reasons, FHWA is proposing to rescind the Manufactured Products General Waiver. The FHWA believes that the Manufactured Products General Waiver is no longer in the public interest. The FHWA seeks comment on whether this is the appropriate course of action. For proponents of rescission, as detailed more below, FHWA seeks comment on when the effective date of the rescission and the implementation of Buy America requirements for manufactured products should be. For opponents of rescission, FHWA similarly seeks comment on when in the future, if ever, the waiver should be rescinded and what factors should FHWA consider before doing so.

V. FHWA Proposed Buy America Manufactured Product Standards

As set out in 23 U.S.C. 313, FHWA must ensure that all manufactured products used in FHWA-funded projects are produced in the United States. The statutory text does not define when a product is ''produced in the United States.'' As FHWA is proposing to rescind the Manufactured Products General Waiver, FHWA believes it is required by BABA to adopt general standards that meet or exceed those under BABA, which FHWA proposes to do through this rulemaking.

Therefore, while commenters to the 2023 RFC proposed various standards they suggested FHWA should adopt for its application of Buy America requirement for manufactured products, FHWA is proposing to adopt the definition of when a manufactured product is ''produced in the United States'' as found in section 70912(6)(B) of BABA. This would require a manufactured product to be manufactured in the United States and the cost of the components of the manufactured product that are mined, produced, or manufactured in the United States to be greater than 55 percent of the total cost of all components of the manufactured product. While FHWA could legally adopt standards exceeding that found in BABA, such as by setting a higher domestic content threshold than 55 percent, FHWA recognizes the burden that any application of Buy America requirements may place on contracting agencies, contractors, and manufacturers. To minimize that burden to the greatest extent practicable while also maintaining the benefits of Buy America requirements, FHWA is proposing to align its standard for when a manufactured product is ''produced in the United States'' for the purpose of 23 U.S.C. 313 to the one found in section 70912(6)(B) of BABA.

This standard would also provide consistency between FHWA's standard for manufactured products and the standard used by other Federal Agencies that apply BABA. Beyond the requirements of section 70917 of BABA, FHWA believes there is a benefit of consistent application and interpretation between FHWA's Buy America requirements and BABA's domestic content procurement preferences. Consistency minimizes the burden on contracting agencies, contractors, and manufacturers, who can rely on existing systems and processes that they use to comply with BABA when working on FHWA-funded projects. It also allows manufactured products that provide BABA-compliant manufactured products for projects funded by other Federal Agencies to provide those same products on FHWA-funded projects. Consistent definitions further allow for better understanding of applicable requirements, as contracting agencies, contractors, and manufacturers do not have to navigate between multiple, disparate regimes.

The FHWA notes that were the Manufactured Products General Waiver to be rescinded, the requirements of 23 U.S.C. 313(h) would apply to manufactured products. This would mean that the proposed Buy America requirements for manufactured products would apply to all contracts eligible for FHWA financial assistance for a project carried out within the scope of the applicable finding, determination, or decision under NEPA, regardless of the funding source for such contracts, if at least one contract for the project is funded with amounts made available to carry out Title 23, U.S.C. In other words, any Buy America requirements for manufactured products could apply to manufactured products purchased under contracts using only non-Federal funds if those contracts are within the scope of a determination under NEPA that involves an obligation of Title 23, U.S.C. funds.

The FHWA notes that it does not intend for these proposed standards to supplant current FHWA waivers that cover specific manufactured products. The FHWA further notes that its proposed standards are substantively similar to those in FHWA's Electric Vehicle (EV) Charger Waiver,[15] which covers EV chargers, a type of manufactured product, and waives Buy America requirements for chargers under certain circumstances.[16] In particular, FHWA notes that under proposed § 635.410(c)(2)(ii), FHWA intends for a predominantly iron or steel enclosure of an EV charger that is installed in the highway right of way or other real property to be subject to FHWA's existing Buy America requirements for iron or steel. The FHWA believes this aligns with FHWA's EV Charger Waiver, which states that ''[a]ll predominantly steel and iron housing components. . .must meet FHWA's Buy America requirements for steel and iron'' and that ''[t]he cost of any such housing shall be included as a cost of an EV charger's components when calculating whether the cost of components manufactured in the United States exceed 55 percent of the cost of all components.'' *See* 88 FR 10619, 10634 (Feb. 21, 2023).

While FHWA is proposing to discontinue the Manufactured Products General Waiver and impose Buy America requirements on manufactured products, FHWA does not desire to place contracting agencies, contractors, and manufacturers in a position where they are required to comply with Buy America requirements for manufactured products without having the systems in place to do so. For example, when part 184 was issued by OMB in August 2023, a 60-day period was provided before the revised standards for construction materials become effective. A longer transition or adjustment period was provided by DOT following the initiation of the new BABA requirements in May 2022. At that time, DOT issued an adjustment period waiver to allow time for stakeholders to transition to new rules and processes required by BABA related to construction materials. *See* ''Temporary Waiver of Buy America Requirements for Construction Materials,'' at 87 FR 31931. The FHWA seeks comment on whether a similar transition period is needed for its proposed standards for manufactured products to allow contracting agencies, contractors, and manufacturers time to create appropriate systems and processes, as well as train staff on compliance with the proposed standards. The FHWA specifically seeks comment on the minimum time required for these purposes and, accordingly, the effective date for the proposed Buy America requirements for manufactured products.

The FHWA also recognizes the complications that may arise if new requirements are imposed on ongoing projects, as well as projects that are in the planning, design, or later implementation phases. The FHWA intends any new requirements to only apply to Federal awards obligated or authorized after the effective date of a final rule, but FHWA requests comments on this point as well. For instance, FHWA requests comment on whether there should be a buffer period for certain projects that are in development that have not had Federal awards obligated or authorized but have relied on the Manufactured Products General Waiver such that those projects could continue to rely on the Manufactured Products General Waiver, and under what conditions, if any, that buffer period would apply.[17]

The FHWA also recognizes that there are projects for highway construction that are subject to alternate project delivery methods, such as design-build, where contracts are awarded and work is authorized and obligated in phases. For example, where a project has not completed the environmental review process, Federal funds may be obligated for preliminary engineering and environmental document preparation but not physical construction. In these situations, FHWA believes that it may be appropriate to apply these proposed standards, if adopted, to physical construction since Federal funds have not been obligated or authorized for this work nor have there been any contractual commitments with respect to this work. The FHWA also requests comments on the appropriate buffer period, if any, for these types of projects.[18]

The FHWA also understands that tracking the origin and cost of components may be difficult, particularly for smaller manufacturers, contractors, and contracting agencies. To ease this burden, FHWA is not prescribing any specific method of compliance. The FHWA's intent and expectation is that recipients ensure that 55 percent of components, by cost, of a manufactured product are mined, produced, or manufactured in the United States. The FHWA requests comments on any specific provisions that FHWA should consider in easing the administrative burden in demonstrating compliance with this proposed requirement.

VI. Section Analysis

§ 635.410(b), (c), and (d)—Reference to States

The FHWA does not intend to substantively change its current Buy America regulations as they relate to FHWA's Buy America requirement for iron and steel. The FHWA does, however, intend to make several, minor changes regarding these requirements to reflect the current scope of its Buy America requirements.

In § 635.410(b)(2), the introductory paragraph to § 635.410(b)(3), and § 635.410(d), FHWA is proposing to replace the mention of ''State'' with ''recipient.'' Along with the replacement of current § 635.410(c), described below, this would replace all mentions of ''State'' in the current regulation with ''recipient.'' The FHWA's Buy America requirements apply to all recipients of title 23, U.S.C. funds, which includes States but also may include other recipients like metropolitan planning organizations, local governments, and

[15] Waiver of Buy America Requirements for EV Chargers, 88 FR 10619, February 21, 2023.

[16] More guidance on the EV Charger Waiver can be found at *https://www.fhwa.dot.gov/construction/contracts/buyam_qaev/.*

[17] See DOT's Waiver of Buy America Requirements for Construction Materials for Certain Contracts and Solicitations, issued on January 30, 2023, for a recent example of how the Department has handled similar situations for construction materials subject to the BABA requirements. *https://www.transportation.gov/mission/office-secretary/office-policy/transportation-policy/waiver-buy-america-requirements-for-construction-materials.*

[18] Ibid.

regional transportation authorities. As the Buy America requirements are the same between States and non-State entities, FHWA believes non-State entities should have the same abilities provided in regulation as States currently do.

§ 635.410(b)—Reference to Steel or Iron Materials

Currently, 23 CFR 635.410(b) interchangeably refers to ''steel or iron materials'' and ''steel and iron materials.'' For consistency, FHWA is proposing to replace mentions of both terms with a single phrase: ''iron or steel products,'' which would be defined at proposed § 635.410(c)(1)(ii). The FHWA does not intend this change to affect its Buy America requirements for iron or steel materials. As noted in the discussion below with respect to proposed § 635.410(c)(1)(ii) and (iv), and (c)(2), this change would make clear when a manufactured product comprised of steel or iron would be considered an iron or steel product versus a manufactured product. Consistent with current FHWA requirements, predominantly iron or steel products would be subject to FHWA's existing Buy America requirements for iron and steel at § 635.410(b). Manufactured products that are not predominantly iron or steel would be subject to FHWA's proposed Buy America requirements for manufactured products at § 635.410(c).

§ 635.410(c)—Waiver Provisions

The FHWA is proposing to replace current § 635.410(c) with new language detailing FHWA's Buy America requirements for manufactured products, as described in detail in section V and below. The FHWA is thus proposing to remove the current regulatory text in 23 CFR 635.410(c), which discusses the process for requesting a Buy America waiver and the procedures FHWA will take to respond to that request. These provisions have remained substantively unchanged from 1983.[19] Since then, however, Congress has enacted several provisions structuring FHWA's process for issuing Buy America waivers.[20] These statutorily required processes are not covered by the current version of 23 CFR 635.410(c), and FHWA does not find it necessary to modify 23 CFR 635.410(c) to reiterate what is already stated in statute and FHWA guidance.[21]

§ 635.410(c)—Introductory Text

As stated above in section V, FHWA is proposing to require that all manufactured products used and permanently incorporated in FHWA-funded construction [22] projects be produced in the United States. To promote consistency with FHWA's existing Buy America requirements for iron and steel, FHWA proposes to adopt language similar to the current regulatory language in § 635.410(b)(1).

In addition, FHWA is proposing to make clear that its Buy America requirement for manufactured products only applies to products that are permanently incorporated into FHWA-funded projects. The FHWA believes this aligns with FHWA's longstanding practice for iron and steel items and for the treatment of manufactured products covered by BABA. *See* section IV of the Implementation Guidance.

§ 635.410(c)(1)(i)—Definition of Component

The FHWA is proposing to adopt the definition of ''component'' used in part 184. This would define what a component is for the purpose of FHWA's proposed Buy America requirements for manufactured products and for FHWA's proposed definition of an iron or steel product. To provide contracting agencies, contractors, and manufacturers with consistency, FHWA believes it is useful to have similar definitions between FHWA's Buy America requirements and BABA's domestic content procurement preference where practicable.

§ 635.410(c)(1)(ii) and (vi)—Iron or Steel Products

Pursuant to FHWA's current policy, predominantly iron or steel manufactured products must conform with FHWA's Buy America requirements for iron or steel.[23] The FHWA, however, does not currently define what threshold a product has to meet in order to be classified as a predominantly iron or steel product. In this proposed rulemaking, to provide clarity and consistency on this issue, FHWA is proposing to adopt the definitions of ''iron or steel product'' and ''predominantly iron or steel or a combination of both'' in part 184.

With the proposed application of Buy America to both iron or steel products and manufactured products, FHWA believes that it is necessary to provide standards to determine whether a product should be classified as a manufactured product or an iron or steel product, as that determination is significant in understanding which standards apply to the product. While under FHWA's existing Buy America requirements for iron and steel, all manufacturing processes of the iron and steel must occur in the United States, FHWA's proposed standards for manufactured products allow for the inclusion of non-domestic components.

The FHWA proposes to use the definitions of ''iron or steel products'' and ''predominantly of iron or steel or a combination of both'' to classify a product for purposes of Buy America compliance. In adopting the definitions of ''iron or steel products'' and ''predominantly of iron or steel or a combination of both'' used in part 184, FHWA hopes to utilize a single consistent definition to categorize products on a national level, both for all projects included in FHWA-funded projects and all projects subject to BABA. See the explanation below for proposed § 635.410(c)(2) for more information concerning the classification of materials.

§ 635.410(c)(1)(iii)—Definition of Excluded Materials

The FHWA proposes a definition of the term ''excluded material'' that cross-references the definition of the term ''Section 70917(c) material'' found in

[19] The FHWA has made minor amendments to 23 CFR 635.410(c)(1)(ii) when Congress has modified the statutory coverage of its Buy America requirements. Originally, 23 CFR 635.410(c)(1) referenced a waiver of Buy America requirements being possible when steel and cement materials were not produced in the United States in sufficient and reasonably available quantity and of a satisfactory quality. *See* 48 FR at 53104. When Congress subsequently removed coverage for cement, FHWA modified that provision accordingly to remove reference to cement. *See* 49 FR at 18821. And when Congress added coverage for iron, FHWA modified the provision one last time to include mention of iron. 58 FR at 38975. None of these changes, the last of which occurred in 1993, substantially modified the process and procedures described in 23 CFR 635.410(c), however.

[20] The Consolidated Appropriations Act, 2010 (Pub. L. 111–117) required FHWA to make an informal public notice and comment period at least 15 days prior to issuing any Buy America waiver. The SAFETEA–LU Technical Corrections Bill (Pub. L. 110–244) states that if FHWA determines to issue a waiver, it must publish in the **Federal Register** a detailed written justification as to the reasons for the waiver and provide an additional comment period not to exceed 60 days, with that additional comment period not delaying the effectiveness of the waiver. Section 11513 of BIL affirmed that not less than 15 days before issuing a waiver, FHWA must provide notice of the proposed waiver, an opportunity to comment on the proposed waiver, and the reasons for the proposed waiver.

[21] The FHWA maintains guidance describing the information needed to submit a waiver request and the method to do so. *See* Questions #22–27 at *https://www.fhwa.dot.gov/construction/contracts/buyam_qageneral.cfm,* and Question #19 at *https://www.fhwa.dot.gov/construction/contracts/buyam_qa_baba.cfm.*

[22] 23 U.S.C. 101(a)(4) defines ''construction'' to include, in part, any project eligible for assistance under title 23, U.S.C.

[23] See Q&A #12 a *https://www.fhwa.dot.gov/construction/contracts/buyam_qageneral.cfm.*

part 184 at 2 CFR 184.3. Part 184 defines section 70917(c) materials as cement and cementitious materials; aggregates such as stone, sand, or gravel; and aggregate binding agents or additives. More information on the use of this category of materials in this proposed regulation can be found below in the discussion of proposed §§ 635.410(c)(1)(iv) and (c)(2).

§ 635.410(c)(1)(iv)—Manufactured Products and Section 70917(c) Materials

To ensure consistency with BABA, FHWA proposes to use substantively the same definition of ''manufactured product'' as used by OMB in part 184, with slight changes with respect to references to ''construction materials'' and ''section 70917(c) materials'' in that definition which are described below. *See* 2 CFR 184.3.

The FHWA thus proposes to define a ''manufactured product'' using the same language found in paragraph (1) of the definition of the term in part 184. For consistency, FHWA intends to apply this provision in the same way as applied by OMB in part 184. For example, products brought to the work site in an unprocessed or minimally processed state, such as topsoil, compost, and seed, would not be considered manufactured products. *See* 88 FR at 57769. Similarly, non-manufactured or raw materials mixed off of the work site with other non-manufactured or raw materials of similar types would not necessarily result in the mixed material brought to the work site being classified as a manufactured product if it remains in an unprocessed or minimally processed state, such as minimally-processed fill dirt. *See id.*

The FHWA notes that its proposal omits references to construction materials that are found in part 184. The FHWA does not believe it necessary to refer to construction materials in this proposed rulemaking because 23 U.S.C. 313 does not cover construction materials. Since section 70915(b) of BABA directs OMB to issue the applicable standards with respect to determining when a construction material is produced in the United States for the purposes of BABA, FHWA and its recipients will follow the applicable OMB standards and guidance for construction materials.

The FHWA is also proposing to make clear that excluded materials, defined in proposed § 635.410(c)(1)(iii), are not, on their own, manufactured products. The FHWA would not consider excluded materials to be manufactured products and apply the proposed Buy America requirements for manufactured products if the excluded materials have not been combined with different excluded materials, or other materials, to create a manufactured product. *See* 88 FR 57772. This is also consistent with paragraph (2) of the definition of ''manufactured product'' in part 184.

In terms of these excluded materials, FHWA received many comments in the 2023 RFC expressing confusion over the legal effect of section 70917(c) of BABA. By stating that excluded materials are not manufactured products, FHWA seeks to make clear that these materials—standing alone, as delivered to the job site—are not manufactured products. Likewise, FHWA recognizes and follows the OMB guidance specifying that these materials, standing alone, as delivered to the job site are not construction materials either, as provided in section 70917(c) of BABA. *See* 88 FR 57771.

In alignment with part 184, FHWA intends this rulemaking to mean that excluded materials, as defined in proposed § 635.410(c)(1)(iii), when combined together with other materials, including other excluded materials, could result in the creation of a manufactured product. *See id.* at 57772. If the individual excluded material is combined with other excluded materials and non-minor additions of other materials before it is brought to the work site, then the new product should be classified as a manufactured product and the excluded materials should be treated as components of the manufactured products. Therefore, like all other components of manufactured products, when excluded materials are components of a manufactured product, they would generally be included in the determination of whether a manufactured product is Buy America-compliant under FHWA's proposed standards.

For example, in alignment with part 184, the combination of excluded materials and other materials into precast concrete would not render the precast concrete exempt from domestic content procurement preferences. *See id.* at 57771. For precast concrete, FHWA believes such an item would be a manufactured product or an iron or steel item depending on its amount of iron or steel, by cost. In either case, precast concrete used in FHWA-funded projects would be subject to the applicable Buy America requirement.[24] To the extent that cement and cementitious material are components of that precast concrete, their origin and cost would have to be considered to determine whether the precast concrete would be Buy America-compliant.[25] Similarly, in some cases, aggregate binding agents and additives may be treated as components of manufactured products.

While FHWA is proposing that products with excluded materials as their components would generally be considered manufactured products, in alignment with part 184, FHWA also proposes that such excluded materials combined as an unsettled mixture without final form when reaching the work site should not be considered a manufactured product, such as in the case of wet concrete or hot mix asphalt. *See id.* The OMB noted in part 184 that while these products might fit the same definition of ''manufactured products'' FHWA is proposing to use, in the sense that the mixture would have ''different properties'' than would the individual materials, it is more consistent with the intent of BABA to treat only such materials that have set or dried into a particular shape or form prior to reaching the work site as manufactured products. *Id.* The FHWA agrees with OMB and further intends for these proposed regulations to have the same reach as part 184.

In particular, consistent with part 184, FHWA proposes to make clear that concrete and asphalt mixtures delivered to a job site without final form for incorporation into a project shall not be considered a manufactured product. As provided in part 184: ''OMB further clarifies in this preamble that wet concrete should not be considered a manufactured product if not dried or set prior to reaching the work site. The setting or drying of a combination of section 70917(c) materials into a

[24] If considered an iron or steel item, the precast concrete would be subject to FHWA's existing Buy America requirements for iron and steel. If considered a manufactured product, as described below, FHWA is proposing that the precast concrete be subject to the proposed Buy America requirements for manufactured products and that the iron and steel be subject to FHWA's existing Buy America requirements for iron and steel.

[25] The FHWA acknowledges that Congress eliminated a Buy America requirement regarding cement originally included in the 1983 STAA in 1984. *See* Public Law 98–229. The FHWA therefore believes it would be questionable to apply a domestic content procurement preference to cement. As noted above, FHWA does not intend to apply any domestic content procurement preference to cement standing alone, either as a manufactured product or as a construction material under BABA. The FHWA does not believe the removal of cement from the 1983 STAA, however, means that cement must be exempted from Buy America requirements even if included in a manufactured product. The FHWA believes the language of the 1983 STAA can be interpreted to refer to cement as a category of product. Its elimination therefore removes the ability of FHWA to apply a Buy America requirement to cement as a category of product. It says nothing about FHWA's ability to consider it as a component of a manufactured product.

finished product prior to reaching the work site is generally the circumstance in which a combination of only section 70917(c) materials would be considered a manufactured product.'' *See id.* at 57772.

§ 635.410(c)(1)(v)—Definition of ''Manufacturer''

For the purposes of defining the term ''manufacturer'' as it is used in § 635.410(c)(3), FHWA is proposing to use the definition found in part 184 at 2 CFR 184.3. The FHWA believes this definition is simple and provides clarity on how to distinguish between the manufacturer of the finished manufactured product and the manufacturer of the components that go into that product.

§ 635.410(c)(1)(vii)—Definition of ''Produced in the United States''

For the reasons stated in section V, above, FHWA proposes to adopt the definition for ''produced in the United States'' for manufactured products found in section 70912(6)(B) of BABA, as implemented by OMB in part 184 at 2 CFR 184.3.

§ 635.410(c)(2)—Classification

Single Classification of Materials

In § 635.410(c)(2), FHWA is proposing to make clear, consistent with part 184, that an article, material, or supply should only be classified as either an iron or steel product, manufactured product, or another category specified by law or found in 2 CFR part 184. With two exceptions, discussed in more detail below, this means that an article, material, or supply cannot fall into multiple categories, *i.e.,* be classified as both an iron or steel product and a manufactured product. While this proposed regulation would only apply requirements to iron or steel materials and manufactured products, as those are the only materials covered under 23 U.S.C. 313, FHWA is proposing this provision to differentiate iron or steel materials, manufactured products, and other materials referred to in law or in part 184, such as excluded materials, as defined in proposed § 635.410(c)(1)(iii) and known as section 70917(c) materials in part 184, and construction materials, which may be subject to their own domestic content procurement preference. In alignment with part 184, FHWA does not intend to subject a material to multiple Buy America requirements. Nor does FHWA intend to subject a material to a Buy America requirement and the requirement of another domestic content procurement preference, such as requirements for construction materials found in part 184. The FHWA similarly does not intend materials to be subject to a Buy America requirement and the same domestic content procurement preference under BABA. For example, manufactured products would be subject only to FHWA's proposed standards, not both FHWA's proposed standards and the standards under BABA and part 184. In general, FHWA agrees with part 184 that applying multiple requirements to a single product is unnecessarily burdensome.

For instance, except as provided below, FHWA does not generally intend for a manufactured product with limited iron or steel content to be subject to both requirements for iron or steel products and manufactured products. Conversely, FHWA does not intend for a predominantly iron or steel manufactured product, when classified as an iron or steel product, to be subject to the proposed standards for manufactured products. Under FHWA's proposed § 635.410(c)(2), any products meeting the definition of a manufactured product would need to comply with the proposed standards for manufactured products while products meeting the definition of an iron or steel product would continue to comply with FHWA's existing standards for iron or steel products found in 23 CFR 635.410(b).

Nor does FHWA intend for materials properly classified as construction materials under part 184 to be subject to FHWA's Buy America requirements. The FHWA is not proposing to have this regulation cover the requirements applicable to construction materials. Instead, FHWA intends for properly classified construction materials to be solely subject to the requirements in BABA and part 184. Iron or steel products and manufactured products that may contain construction materials, however, would still be subject to the applicable FHWA Buy America requirement. In such cases, FHWA does not intend for such components of the iron or steel product or manufactured product to be subject to BABA's construction material requirements.

Finally, FHWA intends this provision to make clear, as mentioned above in the discussion of proposed § 635.410(c)(1)(iv), that excluded materials, standing alone, would not be subject to FHWA's Buy America requirements for manufactured products. Excluded materials, known as section 70917(c) materials in part 184, are a category of products specified in 2 CFR part 184. The proposed language would indicate that a material could only be classified as either an excluded material or manufactured product; an excluded material could therefore not be a manufactured product by itself.

However, for two particular kinds of manufactured products, FHWA is proposing additional requirements along with FHWA's proposed standards for manufactured products in order to continue FHWA's longstanding policy of requiring predominantly iron or steel components of manufactured products to be Buy America-compliant with respect to those predominantly iron or steel components. In particular, FHWA believes this policy should be continued for (1) the iron or steel components of precast concrete; and (2) iron or steel enclosures of intelligent transportation systems and other electronic hardware systems installed in the highway right-of-way or other real property.[26] The FHWA believes that these products are regularly used in highway construction projects and manufacturers have formed longstanding supply chains to incorporate Buy America-compliant iron or steel components into them. Where these products are considered manufactured products, FHWA proposes that the product must meet the standard for a manufactured product. In addition, unlike all other manufactured products, FHWA is proposing to require the specified iron or steel components of these two products to be compliant with FHWA's existing Buy America requirements for iron and steel. However, to minimize any burden and give credit for using an American-made iron or steel product, FHWA proposes to include the cost of these iron or steel components in the determination of whether 55 percent of the product's components, by cost, are produced in the United States.

Besides the two exceptions noted above for precast concrete and iron or steel enclosures of intelligent transportation systems and other electronic hardware systems installed in the highway right-of-way or other real property, FHWA intends § 635.410(c) to possess the same meaning as 2 CFR 184.4(e). The FHWA also believes its proposed language makes clear that a material incorporated into an infrastructure project must meet the Buy America requirement only for the single category in which it is classified, as generally stated in 2 CFR 184.4(f). Materials would be classified as either (1) iron or steel materials and subject to FHWA's existing Buy America

[26] The FHWA notes that these requirements would only apply if the precast concrete or electronic hardware systems were classified as manufactured products. If they were classified as iron or steel products, such products would need to comply with FHWA's existing Buy America requirements for iron or steel.

requirements for iron or steel found in 23 CFR 635.410(b); (2) manufactured products and subjects to the proposed Buy America requirements for manufactured products; or (3) manufactured products that are also either precast concrete or iron or steel enclosures of intelligent transportation systems and other electronic hardware systems installed in the highway right-of-way or other real property and subject to the proposed Buy America requirements for manufactured products and FHWA's existing Buy America requirements for specified iron or steel components of these two products.

Categorization at the Work Site

The FHWA proposes § 635.410(c)(2) to specify that the classification of an article, material, or supply as being either an iron or steel product or a manufactured product must be based on its status at the time it is brought to the work site for incorporation into an infrastructure project. The FHWA believes it is important to determine when the classification of materials occurs, as some manufactured products might include steel and iron. Depending on when a product is classified for the purpose of applying FHWA's Buy America requirements, the iron or steel component of a manufactured product could be classified as a separate material, and thus be subject to FHWA's Buy America requirements for iron and steel.

To provide consistency, FHWA is proposing this standard to align with the standard used by OMB in part 184 at 2 CFR 184.4(e). The FHWA does not intend this language to mean that FHWA will conduct a compliance check to see if a product is Buy America-compliant when it is brought to the work site; FHWA only intends this language to describe when a product will be categorized as either an iron or steel product or a manufactured product for the purpose of determining which Buy America requirement applies.

§ 635.410(c)(3)—Cost of a Component

The FHWA is proposing to adopt the standards, unchanged, used in part 184 at 2 CFR 184.5 to determine the cost of a given component. The FHWA believes that this standard properly includes activities that directly connect to the goals of FHWA's Buy America provision to increase domestic manufacturing. The FHWA also notes that 23 U.S.C. 313(c) specifically states that for the purposes of 23 U.S.C. 313, in calculating components' costs, labor costs included in final assembly must not be included in the calculation.

§ 635.410(c)(4)—Severability

The FHWA is proposing to add a new § 635.410(c)(4) that contains a severability clause applicable to the proposed Buy America requirements for manufactured products made by this proposed rule in § 635.410(c). The FHWA believes that the proposed amendments to § 635.410(c) are capable of operating independently of one another. If one or more aspects of the proposed Buy America requirements for manufactured products are determined to be invalid, the remaining provisions should remain unaffected and in force.

VII. Rulemaking Analysis and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The OMB has determined that the proposed rule would be a significant regulatory action within the meaning of E.O. 12866, as amended by E.O. 14094.

The preliminary regulatory impact analysis (PRIA) supports this proposed regulation and analyzes the costs and benefits associated with establishing Buy America requirements for manufactured products.

The expected benefits of the proposed rule relate to protecting and expanding domestic manufacturing, increasing supply chain resiliency, and increasing consistency in applying domestic content procurement preferences for manufactured products between FHWA and other Federal Agencies that are subject to the requirements of BABA. None of these benefits have been quantified.

The costs of the proposed rule relate to increased material costs for manufactured products used in highway construction projects, project delay, and the administrative costs to FHWA and recipients of FHWA financial assistance. At this time, FHWA is only able to quantify costs for the increased materials costs and the administrative costs to the FHWA. The FHWA's estimates of those increased material costs for manufactured products permanently incorporated into FHWA-funded projects range from a high of roughly $737 million per year to a low of $45 million. The wide range stems from the difficulty in estimating (1) the fraction of inputs to highway construction that are manufactured products; (2) the fraction of manufactured products that are currently domestically supplied but which fail to meet the proposed rule's requirement that 55 percent of the product's components, by cost, are mined, produced, or manufactured in the United States; and (3) the likely price premiums for purchasing manufactured products that would be compliant with the proposed rule compared to manufactured products currently used in FHWA-funded projects that would not be. The FHWA estimates an additional $167,000 per year in increased FHWA administration costs to cover the salary and employer-provided benefits of an additional Federal employee to administer the Buy America program. The other administrative costs to recipients of FHWA financial assistance and the costs associated with project delivery delay have not been quantified.

The full regulatory impact analysis is available in the docket. The FHWA is seeking comment on assumptions that were developed as part of the PRIA, as well as information on other benefits or costs that would result from implementation of the rule.

This rule will not adversely affect in a material way the economy, any sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities. These changes do not create a serious inconsistency with any other Agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this proposed rule on small entities and has determined that it is not anticipated to have a significant economic impact on a substantial number of small entities. This proposed rule would impose Buy America requirements for manufactured products on recipients of FHWA financial assistance including States, local governments, and other grant recipients. These recipients are primarily States, who are not included in the definition of small entity set forth in 5 U.S.C. 601. The FHWA believes the projected impact upon small entities that utilize FHWA funding would be negligible. To the extent the revisions require expenditures by State, local governments, and other grant recipients on Federal-aid projects, they are reimbursable. Small entities that may be impacted indirectly by a rulemaking are not subject to analysis under the Regulatory Flexibility Act, see *Mid-Tex Electric Cooperative, Inc.* v. *Federal Energy Regulatory Commission,* 773 F.2d 327 (D.C. Cir 1985). Therefore,

FHWA certifies that the proposed action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48). Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires Federal Agencies to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. The definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility. Further, in compliance with the Unfunded Mandates Reform Act of 1995, FHWA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the effects on State, local, and Tribal governments, and the private sector.

Executive Order 13132 (Federalism)

The E.O. 13132 requires Agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may 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. The FHWA has analyzed this proposed rule in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this proposed rule would not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this proposed rule would not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal Agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. The FHWA has determined that the proposed rule does not contain collection of information requirements for the purposes of the PRA.

National Environmental Policy Act

The FHWA has analyzed this proposed rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Categorically excluded actions meet the criteria for categorical exclusions under the Council on Environmental Quality regulations and under 23 CFR 771.117(a) and normally do not require any further NEPA approvals by FHWA. This proposed rule would establish Buy America requirements for manufactured products. The FHWA does not anticipate any adverse environmental impacts from this proposed rule, and no unusual circumstances are present under 23 CFR 771.117(b).

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this proposed rule in accordance with the principles and criteria contained in E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' The FHWA does not believe that the proposed rule would have substantial direct effects on one or more Indian Tribes; would not impose substantial direct compliance costs on Indian Tribal governments; and would not preempt Tribal laws. Therefore, a Tribal summary impact statement is not required.

Executive Order 12898 (Environmental Justice)

The E.O. 12898 requires that each Federal Agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. The FHWA has determined that this proposed rule does not raise any environmental justice issues.

Regulation Identification Number

A RIN is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in spring and fall of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

Rulemaking Summary, 5 U.S.C. 553(b)(4)

As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found in the Abstract section of the Department's Unified Agenda entry for this rulemaking at [*https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2125-AG13*].

List of Subjects in 23 CFR Part 635

Grant programs—transportation, Highways and roads, Reporting and recordkeeping requirements.

Shailen P. Bhatt,

Administrator,Federal Highway Administration.

For the reasons stated in the preamble, FHWA proposes to amend part 635, as follows:

PART 635—CONSTRUCTION AND MAINTENANCE

■ 1. The authority citation for part 635 continues to read as follows:

Authority: Sections 1525 and 1303 of Pub. L. 112–141, Sec. 1503 of Pub. L. 109–59, 119 Stat. 1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 *et seq.;* Sec. 1041(a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.85(a)(1).

Subpart D—General Material Requirements

■ 2. Amend § 635.410 by:
■ a. Removing the word ''State'' and adding in its place the word ''recipient'' in paragraphs (b)(2) and (3);
■ b. removing the words ''steel and iron materials'' and ''steel or iron materials'' and adding, in their place, the words ''iron or steel products'' in paragraphs (b)(1)(i) and (ii), (b)(2), (b)(3) introductory text, (b)(3)(i) and (ii), and (b)(4);
■ c. revising paragraph (c); and
■ d. Removing the word ''State'' and adding in its place the word ''recipient'' in paragraph (d).

The revision reads as follows:

§ 635.410 Buy America requirements.

* * * * *

(c) No Federal-aid highway construction project is to be authorized

for advertisement or otherwise authorized to proceed unless the manufactured products used and permanently incorporated in such project are produced in the United States. To meet this requirement, the manufactured product must meet the following:

(1) The following definitions apply to this section:

(i) *Component* means an article, material, or supply, whether manufactured or unmanufactured, incorporated directly into a manufactured product or, where applicable, an iron or steel product.

(ii) *Excluded materials* means *section 70917(c) materials* as defined in 2 CFR 184.3.

(iii) *Iron or steel products* means articles, materials, or supplies that consist wholly or predominantly of iron or steel or a combination of both.

(iv) *Manufactured products* means articles, materials, or supplies that have been processed into a specific form and shape, or combined with other articles, materials, or supplies to create a product with different properties than the individual articles, materials, or supplies. If an item is classified as an iron or steel product, an excluded material, or other product category as specified by law or in 2 CFR part 184, then it is not a manufactured product. However, an article, material, or supply classified as a manufactured product may include components that are iron or steel products, excluded materials, or other product categories as specified by law or in 2 CFR part 184. Mixtures of concrete or asphalt delivered to a job site without final form for incorporation into a project are not a manufactured product.

(v) *Manufacturer,* in the case of manufactured products, means the entity that performs the final manufacturing process that produces a manufactured product.

(vi) *Predominantly of iron or steel or a combination of both* means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components.

(vii) *Produced in the United States,* in the case of manufactured products, means:

(A) The product was manufactured in the United States; and

(B) The cost of the components of the manufactured product that are mined, produced, or manufactured in the United States is greater than 55 percent of the total cost of all components of the manufactured product.

(2) An article, material, or supply shall only be classified as an iron or steel product, a manufactured product, or other products as specified by law or in 2 CFR part 184. An iron or steel product must meet the requirements of paragraph (b) of this section. Except as otherwise provided in this paragraph (c), an article, material, or supply shall not be considered to fall into multiple categories. In some cases, an article, material, or supply may not fall under any of the above-listed categories. The classification of an article, material, or supply as falling into one of the categories listed in this paragraph (c) must be made based on its status at the time it is brought to the work site for incorporation into an infrastructure project. In general, the work site is the location of the infrastructure project at which the iron or steel product or manufactured product will be incorporated.

(i) With respect to precast concrete products that are classified as manufactured products, components of precast concrete products that are manufactured predominantly of iron or steel or a combination of both shall meet the requirements of paragraph (b) of this section. The cost of such components shall be included in the applicable calculation for purposes of determining whether the precast concrete product is produced in the United States.

(ii) With respect to intelligent transportation systems and other electronic hardware systems that are installed in the highway right of way or other real property and classified as manufactured products, the cabinets or other enclosures of such systems that are manufactured predominantly of iron or steel or a combination of both shall meet the requirements of paragraph (b) of this section. The cost of cabinets or other enclosures shall be included in the applicable calculation for purposes of determining whether systems referred to in the preceding sentence are produced in the United States.

(3) In determining whether the cost of components for manufactured products is greater than 55 percent of the total cost of all components, recipients shall determine the cost as follows:

(i) For components purchased by the manufacturer, the acquisition cost, including transportation costs to the place of incorporation into the manufactured product (whether or not such costs are paid to a domestic firm), and any applicable duty (whether or not a duty-free entry certificate is issued); or

(ii) For components manufactured by the manufacturer, all costs associated with the manufacture of the component, including transportation costs as described in paragraph (a) of this section, plus allocable overhead costs, but excluding profit. Cost of components does not include any costs associated with the manufacture of the manufactured product.

(4) The provisions of this paragraph (c) are separate and severable from one another and from the other provisions of this section. If any provision is stayed or determined to be invalid, the remaining provisions shall continue in effect.

* * * * *

[FR Doc. 2024–05182 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–22–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 312

[EPA–HQ–OLEM–2024–0097; FRL–11691–02–OLEM]

Standards and Practices for All Appropriate Inquiries; Notice of Proposed Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the Standards and Practices for All Appropriate Inquiries to reference a standard practice recently made available by ASTM International, a widely recognized standards development organization. Specifically, EPA is proposing to amend the All Appropriate Inquiries Rule to reference ASTM International's E2247–23 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property'' and allow for its use to satisfy the requirements for conducting all appropriate inquiries under the Comprehensive Environmental Response, Compensation, and Liability Act. EPA is additionally proposing to remove after one year, from the All Appropriate Inquiries Rule, recognition of the previous version of that standard, ASTM E2247–16, as compliant with the All Appropriate Inquiries Rule.

DATES: Written comments must be received by April 11, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2024–0097 at *www.regulations.gov:* Follow the on-line

instructions for submitting comments. Once submitted, comments cannot be edited or removed from *regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI and multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For more detailed information on specific aspects of this rule, contact Patricia Overmeyer, Office of Brownfields and Land Revitalization (5105T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460–0002, 202–566–2774, or *Overmeyer.patricia@epa.gov*

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

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I. Why is EPA issuing this proposed rule?

With this action EPA proposes to amend the All Appropriate Inquiries Rule at 40 CFR part 312 to reference ASTM International's E2247–23 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property'' and allow for its use to satisfy the requirements for conducting all appropriate inquiries under CERCLA. EPA also is proposing to sunset its reference to E2247–16, the historic version of the same ASTM standard, as compliant with the All Appropriate Inquiries Rule.

EPA is not proposing any changes to regulatory requirements in the All Appropriate Inquiries Rule. Therefore, EPA is not seeking comments on the standards and practices included in the All Appropriate Inquiries Rule at 40 CFR part 312. EPA is only seeking comments on the Agency's decision to reference the revised ASTM E2247–23 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property'' as compliant with the AAI regulation, and to sunset the reference to the previous version of the standard, ASTM E2247–16 as compliant with the AAI Rule. EPA is not seeking comments on the ASTM E2247–23 standard.

EPA will address all public comments in any subsequent final rule based on this proposed rule. We do not intend to institute a second comment period on this action. Any parties interested in commenting on this proposal must do so at this time. For further information, please see the information provided in the **ADDRESSES** section of this document.

II. Does this action apply to me?

This action offers certain parties the option of using an available industry standard to conduct all appropriate inquiries. Parties purchasing potentially contaminated properties will be able to use the ASTM E2247–23 standard practice to comply with the all appropriate inquiries requirements of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This proposed rule will not require any entity to use this standard. Any party who wants to claim protection from liability under one of CERCLA's landowner liability protections may follow the regulatory requirements of the All Appropriate Inquiries Rule at 40 CFR part 312, use the ASTM's E1527–21 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process,'' or use the standard recognized in this proposed rule, the ASTM E2247–23 standard.

Entities potentially affected by this action, or who may choose to use the newly referenced ASTM standard to perform all appropriate inquiries, include public and private parties who, as bona fide prospective purchasers, contiguous property owners, or innocent landowners, are purchasing potentially contaminated properties and wish to establish a limitation on CERCLA liability in conjunction with the property purchase. In addition, any entity conducting a site characterization or assessment on a property with a brownfields grant awarded under CERCLA section 104(k)(2)(B)(ii) may be affected by this action. This includes state, local, and Tribal governments that receive brownfields site assessment grants. A summary of the potentially affected industry sectors (by North American Industry Classification System (NAICS) codes) is displayed in the table below.

Industry category	NAICS code
Real Estate	531.
Insurance	52412.
Banking/Real Estate Credit	522292.
Environmental Consulting Services.	54162.
State, Local and Tribal Government.	926110, 925120.
Federal Government	925120, 921190, 924120.

The list of potentially affected entities in the above table may not be exhaustive. Our aim is to provide a guide for readers regarding those entities that EPA is aware potentially could be affected by this action. However, this action may affect other entities not listed in the table. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

III. What should I consider as I prepare my comments for EPA?

Direct your comments to Docket ID No. EPA–HQ–OLEM–2024–0097. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

A. Submitting CBI: Do not submit any information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. You can only submit CBI to EPA via U.S. mail at: HQ EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20460. Clearly mark all information that you claim to be CBI. For CBI submitted on 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.

B. Tips for Preparing Your Comments: When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggested alternative.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters or any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *https://www2.epa.gov/edockets/commenting-epa-dockets.*

C. The docket: All documents in the docket are listed in the *www.regulations.gov* index. Certain types of information claimed as CBI, and other information whose disclosure is restricted by statute, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material, such as ASTM International's E2247–23 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property'' will not be placed in EPA's electronic public docket but will be publicly available only in printed form in the official public docket. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the HQ EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460.

IV. Statutory Authority

EPA is proposing to amend the All Appropriate Inquiries Rule that sets Federal standards for the conduct of ''all appropriate inquiries'' at 40 CFR part 312. The All Appropriate Inquiries Rule sets forth standards and practices necessary for fulfilling the requirements of CERCLA section 101(35)(B) as required to obtain CERCLA liability protection and for conducting site characterizations and assessments with the use of brownfields grants per CERCLA section 104(k)(2)(B)(ii).

V. Background

On January 11, 2002, President Bush signed the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Amendments''). In general, the Brownfields Amendments to CERCLA provide funds to assess and cleanup brownfields sites; clarify existing and establish new CERCLA liability provisions related to certain types of owners of contaminated properties; and provide funding to establish or enhance State and Tribal cleanup programs. The Brownfields Amendments revised some of the provisions of CERCLA section 101(35) and limited liability under section 107 for bona fide prospective purchasers and contiguous property owners, in addition to clarifying the requirements necessary to establish the innocent landowner liability protection under CERCLA. The Brownfields Amendments clarified the requirement that parties purchasing potentially contaminated property undertake ''all appropriate inquiries'' into prior ownership and use of property before purchasing the property to qualify for protection from CERCLA liability.

The 2002 Brownfields Amendments to CERCLA required EPA to develop regulations establishing standards and practices for how to conduct all appropriate inquiries. EPA promulgated regulations that set standards and practices for all appropriate inquiries on November 1, 2005 (70 FR 66070). In the regulation, EPA referenced, and recognized as compliant with the rule, the ASTM E1527–05 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Standard Process.'' In December 2008, EPA used a direct final rule to amend the All Appropriate Inquiries Rule to recognize another ASTM standard as compliant, ASTM E2247–08 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property.'' Both standards, the ASTM E1527–05 and the ASTM E2247–08, were subsequently revised by ASTM International, and the revised versions were referenced by EPA as compliant with the All Appropriate Inquiries Rule. EPA referenced the ASTM E1527–13 standard on August 15, 2013 (78 FR 49690), referenced the ASTM E1527–21 Standard on December 15, 2022 (87 FR 76578), and referenced the ASTM E2247–16 standard on September 15, 2017 (82 FR 43310). Currently, the All Appropriate Inquiries Rule (40 CFR part 312) allows for the use of the ASTM E1527–21 standard or the ASTM E2247–16 standard to conduct all appropriate inquiries, in lieu of following requirements included in the Rule.

Recently, ASTM International published a revised standard for conducting Phase I environmental site assessments for forestland or rural properties. This standard, ASTM E2247–23, ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Properties,'' was reviewed by EPA, and determined by EPA to be compliant with the requirements of the All Appropriate Inquiries Rule.

Once this action is final, the All Appropriate Inquiries Rule also will allow for the use of the ASTM E2247–23 standard. The reference to the ASTM E2247–16 will be sunset one year following the publication of a final rule.

VI. What action is EPA taking?

This proposed rule will amend the All Appropriate Inquiries Rule to allow for the use of the ASTM E2247–23 standard to conduct all appropriate inquiries as required under CERCLA for establishing the bona fide prospective purchaser, contiguous property owner, and innocent landowner liability protections.

With this proposed action, parties seeking liability relief under CERCLA's landowner liability protections, as well as recipients of brownfields grants for conducting site assessments, will be considered in compliance with the requirements for all appropriate inquiries if such parties comply with the procedures provided in the ASTM

E2247–23, ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property.'' EPA made the determination that the ASTM E2247–23 Standard is compliant with the All Appropriate Inquiries regulation based upon the Agency's finding, after reviewing the elements of the ASTM standard practice and comparing them to the requirements set forth in the All Appropriate Inquiries Rule.

Also, as part of this proposed action, to avoid any confusion associated with the Agency's recognition of a historical standard no longer recognized by ASTM International as current, or no longer reflecting its current consensus-based or customary business standard, the Agency is proposing to remove its current reference to the ASTM E2247–16 ''Standard Practice for Environmental Site Assessments for Forestland or Rural Property.'' To provide parties with an adequate opportunity to complete any AAI investigations that may be on-going using the ASTM E2247–16 standard at the time that EPA publishes a final rulemaking for this action and to allow all parties sufficient notice to become familiar with the updated industry standard (ASTM E2247–23), the Agency is proposing to a sunset period for the removal of its recognition of the historic standard (ASTM E2247–16) as compliant with all appropriate inquiries. The sunset period for removal of the reference to the ASTM E2247–16 Standard Practice for Environmental Site Assessments for Forestland or Rural Property will be one year from the date on which the Agency publishes a final rule recognizing the updated standard, ASTM E2247–23.

The Agency notes that this action will not require any party to use the ASTM E2247–23 standard. Any party conducting all appropriate inquiries to comply with CERCLA's bona fide prospective purchaser, contiguous property owner, and innocent landowner liability protections may continue to follow the provisions of the All Appropriate Inquiries Rule at 40 CFR part 312, or continue to use the ASTM E1527–21 Phase I Environmental Site Assessment Standard.

This proposed action merely will allow for the use of the ASTM E2247–23 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property'' for those parties purchasing potentially contaminated properties who want to use the ASTM E2247–23 standard in lieu of following specific requirements of the All Appropriate Inquiries Rule.

This proposed action also includes the removal of the current reference in the All Appropriate Inquiries Rule to the ASTM E2247–16 Standard Practice for Environmental Site Assessments for Forestland or Rural Properties as compliant with all appropriate inquiries. EPA is proposing that the removal of the reference to the historic standard will take effect one year following publication of a final rule that includes this proposed action.

The Agency notes that there are no legally significant differences between the regulatory requirements and the ASTM E2247–23 standard. To facilitate an understanding of the slight differences between the All Appropriate Inquiries Rule, the ASTM E2247–23 ''Phase I Environmental Site Assessment Standard for Forestland or Rural Property,'' and the ASTM E1527–21 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process,'' EPA developed, and placed in the docket for this proposed rule, the document ''Comparison of All Appropriate Inquiries Regulation, the ASTM E2247–23 Phase I Environmental Site Assessment Process for Forestland or Rural Property, and ASTM E1527–21 Phase I Environmental Site Assessment Process.'' The document also provides a comparison of the ASTM E2247–23 standard to the ASTM E2247–16 version of the standard.

EPA's proposed action includes no changes to the All Appropriate Inquiries Rule other than to add an additional reference to the new ASTM E2247–23 standard and to sunset the reference to the historic ASTM E2247–16 standard. EPA is *not* seeking comments on the standards and practices included in the All Appropriate Inquiries Rule published at 40 CFR part 312. Also, EPA is *not* seeking comments on the ASTM E2247–23 standard. EPA's only action with this proposed rule is recognition of the ASTM E2247–23 standard as compliant with the All Appropriate Inquiries Rule and sunsetting of recognition of the historic standard and, therefore, it is only this action on which the Agency is seeking comment.

EPA is proposing this action because the Agency wants to provide additional flexibility for brownfields grant recipients or other entities that may benefit from the use of the ASTM E2247–23 standard. We believe that this proposed action will allow for the use of a tailored standard that was developed by a recognized standards developing organization, reviewed by EPA, and determined to be equivalent to the Agency's All Appropriate Inquiries Rule. This action does not disallow the use of the previously recognized ASTM E1527–21 Phase I Environmental Site Assessment Standard, and it will not alter, in anyway, the requirements of the previously promulgated All Appropriate Inquiries Rule. In addition, this proposal potentially will increase flexibility for some parties who may make use of the new standard, without placing any additional burden on those parties who prefer to use either the ASTM E1527–21 standard or follow the requirements of the All Appropriate Inquiries Rule when conducting all appropriate inquiries.

By proposing this action, EPA is fulfilling the intent and requirements of the National Technology Transfer and Advancement Act (NTTAA), Public Law 104–113.

VII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this proposed action is not a ''significant regulatory action'' and is therefore not subject to OMB review. This action merely amends the All Appropriate Inquiries Rule to reference ASTM International's E2247–23 ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property'' and allow for its use to satisfy the requirements for conducting all appropriate inquiries under CERCLA. This action does not impose any requirements on any entity, including small entities. Therefore, pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), after considering the economic impacts of this action on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This action does not contain any unfunded mandates or significantly or uniquely affect small governments as described in Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (63 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this action is exempt from review under Executive Order 12866, this rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply,

Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

This action does involve technical standards. Therefore, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) (NTTAA) apply. The NTTAA was signed into law on March 7, 1996, and, among other things, directs the National Institute of Standards and Technology (NIST) to bring together Federal agencies as well as state and local governments to achieve greater reliance on voluntary consensus standards and decrease dependence on in-house standards. It states that use of such standards, whenever practicable and appropriate, is intended to achieve the following goals: (a) Eliminate the cost to the government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulations; (b) provide incentives and opportunities to establish standards that serve national needs; (c) encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards; and (d) further the policy of reliance upon the private sector to supply government needs for goods and services. The Act requires that Federal agencies adopt private sector standards, particularly those developed by standards developing organizations (SDOs), whenever possible in lieu of creating proprietary, non-consensus standards.

This action is compliant with the spirit and requirements of the NTTAA. This action allows for the use of the ASTM International standard known as Standard E1527–21 and entitled ''Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process.'' By taking this action, EPA is fulfilling the intent and requirements of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 312

Environmental protection, Administrative practice and procedure, Hazardous substances.

Barry N. Breen,

Principle Deputy Assistant Administrator, Office of Land and Emergency Management.

[FR Doc. 2024–05232 Filed 3–11–24; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 89, No. 49
Tuesday, March 12, 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.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request; Reinstatement

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and reinstatement under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by April 11, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service (NASS)

Title: Fast Track Generic Clearance for Qualitative Feedback on Customer Satisfaction Surveys.

OMB Control Number: 0535–0261.

Summary of Collection: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to ensure that our programs are effective and meet our users' needs, the National Agricultural Statistics Service (NASS) seeks to obtain OMB approval for the renewal of this generic clearance to collect qualitative feedback on our products and services. The qualitative information to be collected is intended to provide useful insights on user perceptions and opinions. It is not intended to yield quantitative results that are statistically generalizable to any larger populations.

Annual requests from the Illinois Department of Agriculture (IDOA) to establish numerical measurements of the general level of satisfaction felt by IDOA's customers and clients will be included in this generic information collection request when funded by the IDOA. The results are used by some Bureaus in the IDOA as part of a Public Accountability Report that is submitted to the Illinois Comptroller. In addition, the Bureaus are using the results to help guide their operational management decisions, in particular for training staff

Need and Use of the Information: This collection of information is necessary to enable NASS to obtain feedback in an efficient, timely manner, in accordance with our commitment to improving the quality, usability, and ease of accessing our surveys and public information. This feedback will provide insights into user perceptions, experiences, expectations, and provide an early warning of issues with service; and focus attention on areas where communication, training, or changes in operations might improve delivery of products and services. These collections will allow for ongoing, collaborative, and actionable communications between NASS and its customers and stakeholders. The feedback will also contribute directly to the improvement of program management.

Description of Respondents: Farmers, ranchers, agri-businesses and data users.

Number of Respondents: 120,000.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 8,375.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–05217 Filed 3–11–24; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by April 11, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to

the collection of information unless it displays a currently valid OMB control number.

Foreign Agricultural Service

Title: Food Donation Programs (Food for Progress & Section 416(b)) and McGovern-Dole International Food for Education & Child Nutrition Program.

OMB Control Number: 0551–0035.

Summary of Collection: The U.S. Department of Agriculture's Foreign Agricultural Service (FAS) provides U.S. agricultural commodities to feed millions of hungry people in needy countries through direct donations and concessional programs. USDA food aid may be provided through four program authorities: Food for Progress, section 416(b), the McGovern-Dole International Food for Education and Child Nutrition Program, and Public Law 480 (Pub. L. 480). Of these, only Food for Progress and McGovern-Dole are currently utilized.

Under the section 416(b) and Food for Progress programs (the ''Foreign Donation Programs'') and the McGovern-Dole International Food for Education and Child Nutrition (''McGovern-Dole'') Program, information is gathered from applicants desiring to receive federal awards under the programs to determine the viability of requests for resources to implement activities in foreign countries. Recipients of awards under the programs must submit compliance reports and other information until activities carried out with donated commodities or funds, or local currencies generated from the sale of donated commodities, are completed.

Need and Use of the Information: Information is collected from Recipients to determine its ability to carry out a food aid program, to establish the terms under which commodities will be provided, to monitor the progress of commodity distribution (including how transportation is procured), to monitor the progress of expenditure of monetization funds, and to evaluate both the program's success and the Recipient's effectiveness in meeting intended results.

Description of Respondents: Business-for-not-for-Profit; Private voluntary organizations, cooperatives, colleges and universities, foreign governments, intergovernmental organizations, freight forwarders, ship owners and brokers, and survey companies.

Number of Respondents: 61.

Frequency of Responses: Annually.

Total Burden Hours: 88,548.

Rachelle Ragland-Greene,

Acting Departmental Information Collection Clearance Officer.

[FR Doc. 2024–05239 Filed 3–11–24; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Revolving Loan Fund Financial Report, Form ED–209

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on 12/11/2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Economic Development Administration (EDA), Department of Commerce.

Title: Revolving Loan Fund (RLF) Financial Report.

OMB Control Number: 0610–0095.

Form Number(s): ED–209.

Type of Request: Extension of a currently approved information collection.

Number of Respondents: 1,000.

Average Hours per Response: 3 hours.

Burden Hours: 3,000 hours.

Needs and Uses: The EDA Revolving Loan Fund (RLF) Program, authorized under section 209 of the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3149), has served as an important pillar of EDA investment programs since the establishment of the RLF Program in 1975. The purpose of the RLF Program is to provide regions with a flexible and continuing source of capital, to be used with other economic development tools, for creating and retaining jobs and inducing private investment that will contribute to long-term economic stability and growth. EDA provides RLF grants to eligible recipients (RLF recipients), which include State and local governments, Indian Tribes, and non-profit organizations, to operate a lending program that offers loans with flexible repayment terms, primarily to small businesses in distressed communities that are unable to obtain traditional bank financing. These loans enable small businesses to expand and lead to new employment opportunities that pay competitive wages and benefits.

RLF recipients must submit to EDA RLF Financial Report (Form ED–209), which collects limited performance information that EDA uses to oversee and monitor RLF awards (13 CFR 307.14(a)) and monitor the health of their lending portfolio. EDA currently requires Form ED–209 to be submitted on an annual basis for high-performing RLF awards and on a semi-annual basis for other RLF awards.

Since 2020, when PRA approval for Form ED–209 was last extended, the number of RLF recipients required to report to EDA changed substantially resulting in a net decrease in respondents and hour burden associated with Form ED–209. On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), appropriating $1,500,000,000 in supplemental funds to EDA to ''prevent, prepare for, and respond to coronavirus . . . including for necessary expenses for responding to economic injury as a result of coronavirus.'' EDA used a significant portion of those funds to fund over 350 RLF grants. As a result, the number of respondents required to submit Form ED–209 increased substantially. However, the RLF Act enacted on October 30, 2020, allowed for EDA to release the Federal interest in awards 7 years after final disbursement. The RLF Act has allowed over 380 RLFs to be released from their Federal reporting requirements. Although Form ED–209 is being extended without change, and the estimated amount of time required to complete Form ED–209 remains unchanged at three hours, while the estimated annual burden hours for Form ED–209 is decreasing because of the number of RLF grants and respondents no longer required to complete Form ED–209 following the release of EDA oversight.

Affected Public: EDA RLF grant recipients: State and local governments, Indian Tribes, and non-profit organizations.

Frequency: Semi-annual and Annual.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0610–0095.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–05168 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–808]

Certain Steel Nails From the Sultanate of Oman: Notice of Court Decision Not in Harmony With the Final Results of the Antidumping Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On January 5, 2024, the United States Court of International Trade (CIT) issued its final judgment in *Oman Fasteners, LLC* v. *United States and Mid Continent Steel & Wire, Inc.,* Court No. 22–00348, Slip Op. 24–1 (CIT January 5, 2024) (*Oman Fasteners Slip Op. 24–1*), sustaining the U.S. Department of Commerce's (Commerce) final remand results pertaining to the antidumping duty administrative review on certain steel nails (steel nails) from the Sultanate of Oman (Oman), covering the period of review July 1, 2020, though June 30, 2021. Commerce is notifying the public that the CIT's final judgment is not in harmony with the final results of the administrative review, and that Commerce is amending its final results.

DATES: Applicable January 15, 2024.

FOR FURTHER INFORMATION CONTACT: Dakota Potts, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0223.

SUPPLEMENTARY INFORMATION:

Background

On December 22, 2022, Commerce published its final results in the 2020–2021 antidumping duty administrative review of steel nails from Oman. Commerce applied a margin based on facts available with an adverse inference to sole mandatory respondent Oman Fasteners, LLC (Oman Fasteners), because Oman Fasteners filed an untimely questionnaire response, which Commerce rejected. Oman Fasteners appealed Commerce's *Final Results.* On February 15, 2023, the CIT remanded the *Final Results* to Commerce to permit Oman Fasteners to resubmit the rejected questionnaire response and to calculate a margin based on Oman Fasteners' record information. In its final remand redetermination, issued on July 17, 2023, Commerce calculated a margin of zero percent based on Oman Fasteners' information.[1] On January 5, 2024, the CIT sustained Commerce's *Final Redetermination.*[2]

Timken Notice

In its decision in *Timken,*[3] as clarified by *Diamond Sawblades,*[4] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's January 5, 2024, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* with respect to Oman Fasteners' weighted-average dumping margin as follows:

Producer and exporter	Weighted average dumping margin (percent)
Oman Fasteners, LLC	0.00

Cash Deposit Requirements

Because Oman Fasteners has a superseding cash deposit rate, *i.e.,* there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP). This notice will not affect the current cash deposit rate.

Liquidation of Suspended Entries

The CIT's ruling was appealed on January 8, 2024.[5] In the event the CIT's ruling is upheld by a final and conclusive court decision, where an import-specific *ad valorem* assessment rate is zero or *de minimis,*[6] Commerce intends to instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e), and 777(i)(1) of the Act.

Dated: March 6, 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. 2024–05173 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–858]

Certain Softwood Lumber From Canada: Final Results of Countervailing Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On January 16, 2024, the U.S. Department of Commerce (Commerce) published the notice of initiation and preliminary results of a changed circumstances review (CCR) of the countervailing duty (CVD) order on certain softwood lumber from Canada. For these final results, Commerce continues to find that Interfor

[1] *See Final Results of Redetermination Pursuant to Court Remand, Oman Fasteners, LLC* v. *United States,* Court No. 22–00348 (CIT February 15, 2023), dated July 17, 2023 (*Final Redetermination*), available at *https://access.trade.gov/resources/remands/23-17.pdf.*

[2] *See Oman Fasteners Slip Op. 24–1.*

[3] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[4] *See Diamond Sawblades Mfrs. Coal.* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[5] *See Oman Fasteners Slip Op. 24–1,* appeal docketed, No. 2024–1350 (Fed. Cir. January 8, 2024).

[6] *See* 19 CFR 351.106(c)(2).

Corporation, EACOM Timber Corporation, Chaleur Forest Products Inc., and Chaleur Forest Products LP are cross-owned entities in the context of the CVD order on certain softwood lumber from Canada.

DATES: Applicable March 12, 2024.

FOR FURTHER INFORMATION CONTACT: Samuel Brummitt, 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) 482–7851.

SUPPLEMENTARY INFORMATION:

Background

On January 16, 2024, Commerce published the *Preliminary Results,* finding that the following companies are cross-owned entities: Interfor Corporation; EACOM Timber Corporation; Chaleur Forest Products Inc.; and Chaleur Forest Products LP.[1] In the *Preliminary Results,* we provided interested parties an opportunity to comment and request a public hearing regarding Commerce's preliminary findings. The petitioner [2] submitted comments agreeing with our preliminary findings, and we received no other comments from interested parties.[3] Additionally, we received no requests for a public hearing from interested parties.

Scope of the Order

The merchandise covered by this *Order* is softwood lumber, siding, flooring, and certain other coniferous wood (softwood lumber products). For a complete description of the scope of the *Order, see* the *Preliminary Results* PDM.

Final Results of Changed Circumstances Review

For the reasons stated in the *Preliminary Results,* and because we received no comments from interested parties to the contrary, Commerce continues to find that Interfor Corporation, EACOM Timber Corporation, Chaleur Forest Products Inc., and Chaleur Forest Products LP are cross-owned entities.[4] Because our findings remain unchanged from the *Preliminary Results,* no decision memorandum accompanies this notice. We are adopting the *Preliminary Results* as the final results in this CCR. *See* the *Preliminary Results* PDM for a complete discussion of our findings.

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of 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 notice is published in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Tariff Act of 1930, as amended, and 19 CFR 351.216(e), 351.221(b), and 351.221(c)(3).

Dated: March 6, 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. 2024–05223 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Softwood Lumber from Canada: Preliminary Results of Changed Circumstances Review,* 89 FR 2583 (January 16, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] The petitioner is the COALITION, an *ad hoc* association whose members are: U.S. Lumber Coalition, Inc.; Collum's Lumber Products, L.L.C.; Fox Lumber Sales, Inc.; Hankins, Inc.; Pleasant River Lumber Company; PotlatchDeltic; S.I. Storey Lumber Co., Inc.; Stimson Lumber Company; Swanson Group; Weyerhaeuser Company; Giustina Land and Timber Company; and Sullivan Forestry Consultants, Inc.

[3] *See* Petitioner's Letter, ''Petitioner's Letter in Lieu of Case Brief,'' dated January 26, 2024.

[4] However, as Commerce noted in the *Preliminary Results,* these cross-ownership findings do not speak to the applicable cash deposit rates of the relevant entities. *See Preliminary Results,* 89 FR at 2584 and PDM at footnote 36.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–084, C–570–085]

Certain Quartz Surface Products From the People's Republic of China: Expansion of the Period of Review and Supplemental Opportunity To Request Administrative Review; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published notice in the **Federal Register** of February 26, 2024, in which Commerce expanded the period of review (POR) for the current antidumping duty (AD) and countervailing duty (CVD) administrative reviews of certain quartz surface products (quartz surface products) from the People's Republic of China (China) to include entries suspended by the final scope ruling on Malaysian processed quartz slab prior to the current POR of the instant reviews. Commerce additionally provided a supplemental opportunity for interested parties to request a review of certain companies currently ineligible for the scope certification process. This notice incorrectly stated the start of the AD and CVD PORs.

FOR FURTHER INFORMATION CONTACT: Ajay K. Menon, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0208.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 26, 2024, in FR Doc 2024–03857, on page 14055, in the third column, and 14056, in the first column, correct the dates of the expanded POR to be November 4, 2021, through June 30, 2023, for the AD administrative review; and November 4, 2021, through December 31, 2022, for the CVD administrative review.

Background

On February 26, 2024, Commerce published in the **Federal Register** a notice expanding the PORs of the AD and CVD administrative reviews of quartz surface products from China and providing a supplemental opportunity for interested parties to request a review of certain companies currently ineligible for the scope certification process.[1] We incorrectly stated the starting dates of the expanded PORs for these administrative reviews.

Notification to Interested Parties

This notice is issued and published in accordance with section 751 of the Tariff Act of 1930, as amended.

Dated: March 6, 2024.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2024–05225 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Quartz Surface Products from the People's Republic of China: Expansion of the Period of Review and Supplemental Opportunity To Request Administrative Review,* 89 FR 14055 (February 26, 2024).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Notice of Court Decision Not in Harmony With the Final Results of Countervailing Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On February 20, 2024, the U.S. Court of International Trade (CIT) issued its final judgment in *Hyundai Steel Co.* v. *United States,* Court No. 21–00304, sustaining the U.S. Department of Commerce (Commerce)'s remand results pertaining to the administrative review of the countervailing duty (CVD) order on certain corrosion-resistant steel products (CORE) from the Republic of Korea (Korea) covering the period January 1, 2018, through December 31, 2018 (POR). Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to the countervailable subsidy rate assigned to Hyundai Steel Company (Hyundai).

DATES: Applicable March 1, 2024.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo, 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) 482–2371.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2021, Commerce published its *Final Results* of the 2018 CVD administrative review of CORE from Korea.[1] Commerce determined that Hyundai received countervailable subsidies from the Government of Korea (GOK) under various programs, including the Reduction for Sewerage Fees program and the Provision of Port Usage Rights at the Port of Incheon program.[2] With respect to the sewerage fees program, we found that Hyundai's reduced sewerage bill reflected revenue forgone, and we calculated a 0.01 percent *ad valorem* subsidy rate for the program.[3] With respect to the Port of Incheon program, we found that Hyundai received a financial contribution in the form of revenue forgone, because the GOK gave Hyundai the right to collect berthing income and harbor facility usage fees which otherwise would have been collected by the GOK. We calculated a 0.01 percent *ad valorem* subsidy rate for the Port of Incheon program.[4]

Hyundai appealed Commerce's *Final Results.* On January 11, 2022, the CIT, at Commerce's request, remanded Commerce's determination related to the sewerage fees program.[5] Thus, in its first remand redetermination, issued April 11, 2022, Commerce reexamined the Reduction for Sewerage Fees program and determined that the program was not countervailable. On September 26, 2023, the CIT sustained Commerce's first remand determination, and further remanded Commerce's final determination that the Port of Incheon program conferred a benefit.[6] In its second remand redetermination, issued January 24, 2024, Commerce reexamined the Port of Incheon program and determined that the program does not provide a measurable benefit. As a result of these two remand redeterminations, we adjusted the final subsidy rate calculation from the previous rate of 0.51 percent for Hyundai to a new subsidy rate of 0.49 percent.[7] On February 20, 2024, the CIT sustained Commerce's second remand redetermination.[8]

Timken Notice

In its decision in *Timken,*[9] as clarified by *Diamond Sawblades,*[10] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to sections 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's February 20, 2024, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* with respect to the subsidy rate assigned to Hyundai as follows:

Company	Subsidy rate (percent ad valorem)
Hyundai Steel Company	* 0.49

* De minimis.

Cash Deposit Requirements

Because Hyundai has a superseding cash deposit rate, *i.e.,* there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP). This notice will not affect the current cash deposit rate for Hyundai.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined by CIT order from liquidating entries that: were produced and/or exported by Hyundai Steel Co., Ltd., (a/k/a Hyundai Steel Company or Hyundai Steel), and were entered, or withdrawn from warehouse, for consumption during the period January 1, 2018, through December 31, 2018. These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

In the event the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision, Commerce intends to instruct CBP to assess countervailing duties on unliquidated entries of subject merchandise produced and/or exported by Hyundai Steel in accordance with 19 CFR 351.212(b). We will instruct CBP to assess countervailing duties on all appropriate entries covered by this review when the *ad valorem* rate is not zero or *de minimis.* Where an *ad valorem* subsidy rate is zero or *de minimis,*[11] we will instruct CBP to liquidate the appropriate entries without regard to countervailing duties.

[1] *See Certain Corrosion-Resistant Steel Products from the Republic of Korea: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2018,* 86 FR 29237 (June 1, 2021) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM).

[2] *See Final Results* IDM at Comments 2 and 3.

[3] *Id.* at 6–7 and Comment 3.

[4] *Id.* at 7 and Comment 2.

[5] *See Hyundai Steel Co.* v. *United States,* Court No. 21–00304, ECF No. 26 (CIT January 11 2022).

[6] *Hyundai Steel Co.* v. *United States,* 658 F. Supp. 3d 1331 (CIT September 26, 2023).

[7] *See Final Results of Redetermination Pursuant to Court Remand, Hyundai Steel Co.* v. *United States,* Court No. 21–00304 (CIT January 11, 2022), dated April 11, 2022; *see also, Final Results of Redetermination Pursuant to Court Remand, Hyundai Steel Co.* v. *United States,* Court No. 21–00304, Slip Op. 23–142 (CIT September 26, 2023), dated January 23, 2024.

[8] *See Hyundai Steel Company* v. *United States,* Court No. 21–00304, ECF No. 60 (CIT Feb. 20, 2024).

[9] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[10] *See Diamond Sawblades Manufacturers Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[11] *See* 19 CFR 351.106(c)(2).

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: March 6, 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. 2024–05170 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–126; C–570–127]

Non-Refillable Steel Cylinders From the People's Republic of China: Final Affirmative Determination of Circumvention of the Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that non-refillable steel cylinders with water capacities between 100 and 299 cubic inches produced in the People's Republic of China (China) and exported to the United States, are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on certain non-refillable steel cylinders (non-refillable cylinders) from China.

DATES: Applicable March 12, 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 May 11, 2021, Commerce published in the **Federal Register** the AD and CVD orders on non-refillable cylinders from China.[1] On June 1, 2023, Commerce published the initiation of this circumvention inquiry.[2] On November 21, 2023, Commerce published the affirmative *Preliminary Determination* of the circumvention inquiry of the AD and CVD *Orders* on non-refillable cylinders from China with respect to non-refillable cylinders with water capacities between 100 and 299 cubic inches produced in China and exported to the United States.[3] Although we invited parties to comment on the *Preliminary Determination* of this inquiry, we received no comments. Commerce conducted this circumvention inquiry pursuant to section 781(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.226(j).

Scope of the Orders

The merchandise covered by these *Orders* is certain seamed (welded or brazed), non-refillable steel cylinders meeting the requirements of, or produced to meet the requirements of, U.S. Department of Transportation (USDOT) Specification 39, TransportCanada Specification 39M, or United Nations pressure receptacle standard ISO 11118 and otherwise meeting the description provided below (non-refillable steel cylinders). The subject non-refillable steel cylinders are portable and range from 300-cubic inch (4.9 liter) water capacity to 1,526-cubic inch (25 liter) water capacity. Subject non-refillable steel cylinders may be imported with or without a valve and/or pressure release device and unfilled at the time of importation. Non-refillable steel cylinders filled with pressurized air otherwise meeting the physical description above are covered by these *Orders.*

Specifically excluded are seamless non-refillable steel cylinders.

The merchandise subject to these *Orders* is properly classified under statistical reporting numbers 7311.00.0060 and 7311.00.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). The merchandise may also enter under HTSUS statistical reporting numbers 7310.29.0025 and 7310.29.0050. Although the HTSUS statistical reporting numbers are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Merchandise Subject to the Circumvention Inquiry

This circumvention inquiry covers non-refillable cylinders with water capacities between 100 and 299 cubic inches produced in China and exported to the United States.

Statutory and Regulatory Framework

We conducted this circumvention inquiry pursuant to section 781(c) of the Act and 19 CFR 351.226(j). For a complete description of the methodology underlying the *Preliminary Determination, see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Affirmative Final Determination of Circumvention

As detailed in the *Preliminary Determination,* we determine that non-refillable cylinders with water capacities between 100 and 299 cubic inches 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 *Orders,* pursuant to section 781(c) of the Act and 19 CFR 351.226(j). Commerce continues to apply this affirmative circumvention finding on a country-wide basis. Because we received no comments regarding our *Preliminary Determination,* our final determination remains unchanged from our *Preliminary Determination,* and no memorandum accompanies this notice. Therefore, we determine that it is appropriate to include this merchandise within the scope of the *Orders* and to instruct U.S. Customs and Border Protection (CBP) to continue to suspend any entries of non-refillable cylinders with water capacities between 100 and 299 cubic inches produced in China and exported to the United States.

Suspension of Liquidation and Cash Deposit Requirements

In accordance with 19 CFR 351.226(l)(3), based on this final determination in this circumvention inquiry, Commerce will direct CBP to begin or continue to suspend liquidation and to require cash deposits of estimated duties equal to the AD and CVD rates in effect for non-refillable cylinders from China with water capacities between 100 and 299 cubic inches produced in China and exported

[1] *See Certain Non-Refillable Steel Cylinders from the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping Duty and Countervailing Duty Orders,* 86 FR 25839 (May 11, 2021) (*Orders*).

[2] *See Non-Refillable Steel Cylinders from the People's Republic of China: Initiation of Circumvention Inquiry of the Antidumping and Countervailing Duty Orders; Water Capacities Between 100 and 299 Cubic Inches,* 88 FR 35839 (June 1, 2023) (*Initiation Notice*).

[3] *See Non-Refillable Steel Cylinders from the People's Republic of China: Affirmative Preliminary Determination of Circumvention of the Antidumping and Countervailing Duty Orders,* 88 FR 81051 (November 21, 2023) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

to the United States that are entered, or withdrawn from warehouse, for consumption on or after June 1, 2023 (*i.e.,* the date of the initiation of this inquiry).[4] The suspension of liquidation and cash deposit requirements will remain in effect until further notice.

Administrative Protective Order

This notice will serve as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing this affirmative final determination of circumvention in accordance with sections 781(c) of the Act and 19 CFR 351.226(g)(2).

Dated: March 6, 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. 2024–05227 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–836]

Light-Walled Rectangular Pipe and Tube From Mexico: Final Results of Antidumping Duty Administrative Review; 2021–2022

SUMMARY: The U.S. Department of Commerce (Commerce) determines that sales of light-walled rectangular pipe and tube (LWRPT) from Mexico were made at less than normal value during the period of review (POR), August 1, 2021, through July 31, 2022.

DATES: Applicable March 12, 2024.

FOR FURTHER INFORMATION CONTACT: John Conniff or Charles Doss, 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) 482–1009 or (202) 482–4474, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 8, 2023, Commerce published the *Preliminary Results* for this review in the **Federal Register** and invited interested parties to comment on those results.[1] From January 22 to 29, 2024, interested parties submitted case and rebuttal briefs.[2] For a complete summary of events that have occurred since Commerce published the *Preliminary Results,* as well as a full discussion of the issues raised by parties for these final results, *see* the Issues and Decision Memorandum.[3] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The products covered by the *Order* are LWRPT from Mexico. For a complete description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum.[5] A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum is attached in an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* we made certain changes to the preliminary weighted-average dumping margins calculated for Maquilacero/TEFLU, and Regiopytsa. For a detailed discussion of these changes, *see* the Issues and Decision Memorandum.[6]

Rates for Companies Not Selected for Individual Examination

The statute and Commerce's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides for calculating the all-others rate in an investigation, for guidance when calculating the rate for companies which Commerce did not examine in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available.

For these final results of review, we calculated a weighted-average dumping margin for both respondents, Maquilacero/TEFLU and Regiopytsa that are not zero, *de minimis,* or based entirely on the basis of facts available. Accordingly, consistent with section 735(c)(5)(A) of the Act, we determined the weighted-average dumping margin for each of the non-selected companies based on the weighted-average dumping margins calculated for the mandatory respondents.[7]

Final Results of Review

Commerce determines that the following weighted-average dumping

[4] *See Initiation Notice.*

[1] *See Light-Walled Rectangular Pipe and Tube from Mexico: Preliminary Results and Partial Rescission of the Antidumping Duty Administrative Review; 2021–2022,* 88 FR 62056 (September 8, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Nucor Tubular Products Inc. (Nucor)'s Letter, ''Case Brief,'' dated January 22, 2024; *see also* Maquilacero S.A. de C.V.'s (Maquilacero)'s Letter, ''Case Brief;'' dated January 22, 2024; Perfiles LM, S.A. de C.V.'s Letter, ''Case Brief;'' dated January 22, 2024; Productos Laminados de Monterrey S.A. de C.V. and its affiliated U.S. reseller, Prolamsa, Inc (jointly, Prolamsa)'s Letter, ''Rebuttal Brief;'' Nucor's Letter, ''Rebuttal Brief,'' dated January 29, 2024; and Regiomontana de Perfiles y Tubos S. de R.L. de C.V. (Regiopytsa)'s Letter, ''Rebuttal Brief,'' dated January 29, 2024.

[3] *See* Memorandum, ''Light-Walled Rectangular Pipe and Tube from Mexico: Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Light-Walled Rectangular Pipe and Tube from Mexico, the People's Republic of China, and the Republic of Korea: Antidumping Duty Orders; Light-Walled Rectangular Pipe and Tube from the Republic of Korea: Notice of Amended Final Determination of Sales at Less Than Fair Value,* 73 FR 45403 (August 5, 2008) (*Order*).

[5] *See* Issues and Decision Memorandum.

[6] *Id.*

[7] *See* Memorandum, ''Final Results of the Antidumping Duty Administrative Review of Light-Walled Rectangular Pipe and Tube from Mexico: Calculation of the Rate for Non-Selected Respondents,'' dated concurrently with this notice.

margins exist for the period August 1, 2021, through July 31, 2022:

Exporter or producer	Weighted-average dumping margin (percent)
Maquilacero S.A. de C.V./Tecnicas de Fluidos S.A. de C.V	2.64
Regiomontana de Perfiles y Tubos S. de R.L. de C.V	1.36
Aceros Cuatro Caminos S.A. de C.V	2.00
Arco Metal S.A. de C.V	2.00
Fabricaciones y Servicios de Mexico	2.00
Galvak, S.A. de C.V	2.00
Grupo Estructuras y Perfiles	2.00
Industrias Monterrey S.A. de C.V	2.00
Internacional de Aceros, S.A. de C.V	2.00
Nacional de Acero S.A. de C.V	2.00
PEASA-Productos Especializados de Acero	2.00
Perfiles LM, S.A. de C.V	2.00
Productos Laminados de Monterrey S.A. de C.V	2.00
Talleres Acero Rey S.A. de C.V	2.00
Ternium Mexico S.A. de C.V	2.00
Tuberias Aspe S.A de C.V	2.00
Tuberia Laguna, S.A. de C.V	2.00
Tuberias y Derivados S.A. de C.V	2.00

Disclosure

Commerce intends to disclose the calculations performed for these final results to interested parties in this 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 section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. In accordance with 19 CFR 351.212(b)(1), where the respondents reported the entered value of their U.S. sales, Commerce calculated importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales. Where the respondents did not report entered value, we calculated a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total quantity associated with those sales. To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also calculated an importer-specific *ad valorem* ratio based on estimated entered values. Where either a respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR for which the examined companies did not know that the merchandise they sold to an intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

The assessment rate for antidumping duties for each of the companies not selected for individual examination will be equal to the weighted-average dumping margin identified above in the ''Final Results of Review'' section.

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[8]

Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register** in accordance with 19 CFR 356.8(a).

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 by section 751(a)(2)(C) of the Act: (1) the cash deposit rates for the companies identified above in the ''Final Results of Review'' will be equal to the company-specific weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by a company not covered in this administrative review but covered in a completed prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review or completed prior segment of this proceeding but the producer is, the cash deposit rate will be the company-specific rate established for the most recently-completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 3.76 percent, the rate established in the investigation of this proceeding.[9]

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties

[8] *See* section 751(a)(2)(C) of the Act.

[9] *See Order,* 73 FR at 45405

has occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. 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 the term of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: March 6, 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. Changes Since the Preliminary Results
V. Discussion of Issues
Comment 1: Whether Products Sold by TEFLU are In-Scope Merchandise
Comment 2: Whether Commerce Should Modify the Product Characteristics Used in Model Matching
Comment 3: Whether Commerce Should Alter its Treatment of Level of Trade (LOT) Fields in the Margin Program
Comment 4: Whether Commerce Should Remove TEFLU's Sample Sales from Maquilacero/TEFLU's Margin Calculation
Comment 5: Whether Commerce Should Remove Date of Payment and Credit Expense Adjustments from its Margin Calculation
Comment 6: Whether Commerce Must Adjust its Differential Pricing Analysis for Maquilacero/TEFLU
Comment 7: Adjustment of Maquilacero's Domestic Brokerage and Handling (B&H) Charges
Comment 8: Whether Commerce Should Use Updated Financial Statements
Comment 9: Whether Commerce Should Reject Regiopytsa's Change in Depreciation Methodology
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Comment 11: Whether Commerce Should Revise the Scrap Offset
Comment 12: Whether Commerce Should Revise Regiopytsa's General and Administrative (G&A) Expenses
Comment 13: Whether Commerce Should Rely on a Different Methodology for Assigning a Weighted-Average Dumping Margin to Perfiles
VI. Recommendation

[FR Doc. 2024–05221 Filed 3–11–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–016]

Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that the exporters of passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (China) listed in the ''Final Results of Review'' section below, sold subject merchandise at less than normal value during the period of review (POR), August 1, 2021, through July 31, 2022. Further, we also determine that certain companies under review had no shipments of subject merchandise to the United States during the POR.

DATES: Applicable March 12, 2024.

FOR FURTHER INFORMATION CONTACT: Caroline Carroll or Terre Keaton Stefanova, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4948 or (202) 482–1280, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 7, 2023, we published the *Preliminary Results* and invited interested parties to comment.[1] On December 4, 2023, Commerce extended the deadline of the final results of this administrative review to March 5, 2024, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(h)(2).[2] For details regarding the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Order[4]

The products covered by this *Order* are certain passenger vehicle and light truck tires from China. For a complete description of the scope of the *Order, see* the *Preliminary Results.*

Analysis of Comments Received

We addressed all the issues raised in the case and rebuttal briefs in the Issues and Decision Memorandum. A list of the issues that parties raised is provided in Appendix I of this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on comments received from interested parties regarding the *Preliminary Results,* we have made certain changes to the margin calculations for Giti and Sumitomo.[5] For a discussion of these changes, *see* the Issues and Decision Memorandum.

[1] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission, and Preliminary Determination of No Shipments; 2021–2022,* 88 FR 61506 (September 7, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of 2021–2022 Antidumping Duty Administrative Review,'' dated December 4, 2023.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China and Final Determination of No Shipments; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice.

[4] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015) (*Order*).

[5] Giti consists of the following companies: Giti Tire Global Trading Pte. Ltd.; Giti Radial Tire (Anhui) Company Ltd.; Giti Tire (Fujian) Company Ltd.; Giti Tire (Hualin) Company, Ltd.; Giti Tire Greatwall Company. Ltd.; Giti Tire (Anhui) Company; Giti Tire (Yinchuan) Company Ltd.; and Giti Tire (Chongqing) Company Ltd. (collectively, Giti). Sumitomo consists of the following companies: Sumitomo Rubber (Hunan) Co., Ltd.; Sumitomo Rubber (Changshu) Co., Ltd. (SRC); and Sumitomo Rubber Industries Ltd. (collectively, Sumitomo).

Final Determination of No Shipments

In the *Preliminary Results,* we determined that the following companies did not have shipments of subject merchandise during the POR: (1) Crown International Corporation; (2) Prinx Chengshan (Shandong) Tire Company, Ltd.; (3) Qingdao Nama Industrial Co., Ltd.; (4) Shandong Changfeng Tyres Co., Ltd.; (5) Shandong Duratti Rubber Corporation Co., Ltd.; (6) Shandong Transtone Tyre Co., Ltd.; (7) Shandong Yongsheng Rubber Group Co., Ltd.; and (8) Triangle Tyre Co., Ltd. (Triangle Tyre).[6] We received comments from the petitioner[7] and Triangle Tyre regarding the no-shipments claim for Triangle Tyre.[8] However, we continue to find that each of the above-listed companies had no shipments of subject merchandise during the POR and we will issue appropriate liquidation instructions consistent with our ''automatic assessment'' clarification for these final results.[9]

Separate Rates

In the *Preliminary Results,* we found that Zhongce Rubber Group Co., Ltd. (Zhongce) did not establish its eligibility for a separate rate.[10] Moreover, we determined that 14 other companies under review did not establish their eligibility for a separate rate because they failed to provide either a separate rate application, a separate rate certification, or a no-shipment certification (if they were already eligible for a separate rate). As such, we preliminarily determined that Zhongce and these 14 other companies are part of the China-wide entity. No party filed comments on these determinations in the *Preliminary Results.* Therefore, for the final results, we continue to find that these 15 companies are part of the China-wide entity. *See* Appendix III for a complete list of these 15 companies.

In the *Preliminary Results,* we determined that Giti, Sumitomo, and 12 other companies demonstrated their eligibility for separate rates.[11] No party filed comments on these determinations in the *Preliminary Results.* Therefore, we made no changes to our preliminary separate rate findings and we continue to find that Giti, Sumitomo, and the 12 companies listed in Appendix II have demonstrated their eligibility for a separate rate in this review.

Rate for Non-Selected Separate Rate Respondents

The Act and Commerce's regulations do not address what rate to apply to respondents not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for non-selected respondents that are not examined individually in an administrative review. Section 735(c)(5)(A) of the Act states that the all-others rate should be calculated by averaging the weighted-average dumping margins for individually examined respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available. When the rates for individually examined companies are all zero, *de minimis,* or based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use ''any reasonable method'' to establish the all-others rate. Accordingly, for these final results, we calculated a simple average of the dumping margin for the separate rate respondents using the calculated rates of the mandatory respondents, Giti and Sumitomo, which are not zero, *de minimis,* or determined entirely on the basis of facts available. *See* Appendix II for the list of these companies.

Final Results of Review

We are assigning the following dumping margins to the firms listed below for the period August 1, 2021, through July 31, 2022:

Exporter	Weighted-average dumping margin (percent)
Giti Tire Global Trading Pte. Ltd.; Giti Radial Tire (Anhui) Company Ltd.; Giti Tire (Fujian) Company Ltd.; Giti Tire (Hualin) Company Ltd.; Giti Tire Greatwall Company, Ltd.; Giti Tire (Anhui) Company, ltd.; Giti Tire (Yinchuan) Company, Ltd.; and Giti Tire (Chongqing) Company, Ltd	53.41
Sumitomo Rubber Industries Ltd.; Sumitomo Rubber (Hunan) Co., Ltd.; and Sumitomo Rubber (Changshu) Co., Ltd	2.47
Separate Rate Companies[12]	27.94

Disclosure

Commerce intends to disclose the calculations performed in connection with these final results to interested parties 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 section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. 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).

For Giti and Sumitomo, we calculated importer-specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for each importer's examined sales and the total entered value of the sales, in accordance with 19 CFR 351.212(b)(1). Where either a respondent's weighted-average dumping margin is zero or *de minimis,* within the meaning of 19 CFR 351.106(c)(1) of the Act, or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.

[6] *See Preliminary Results,* 88 FR at 61507.

[7] The petitioner is the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC.

[8] *See* the Issues and Decision Memorandum at Comment 7 for a discussion of the comments received regarding Triangle Tyre's no-shipment claim.

[9] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) (*Non-Market Economy Assessment Notice*).

[10] *See Preliminary Results* PDM at 11.

[11] *Id.* at 10.

[12] *See* Appendix II for the list of these companies.

Pursuant to Commerce's assessment practice,[13] for entries that were not reported in the U.S. data submitted by Giti and Sumitomo, we will instruct to CBP to liquidate such entries at the China-wide rate (*i.e.,* 76.46 percent).[14] Additionally, where Commerce determined that an exporter under review had no shipments of subject merchandise to the United States during the POR, any suspended entries of subject merchandise that entered under that exporter's CBP case number during the POR will be liquidated at the weighted-average dumping margin assigned to the China-wide entity.

For respondents not individually examined in this administrative review that qualified for a separate rate, the assessment rate will be equal to the simple average of the dumping margin calculated using the rates assigned to Giti and Sumitomo in these final results.

For the companies found not eligible for a separate rate and part of the China-wide entity, we will instruct CBP to liquidate all entries of subject merchandise during the POR exported by these companies at the China-wide assessment rate of 76.46 percent.

Cash Deposit Requirements

The following cash deposit requirements will be effective for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date for the final results of review, as provided for by section 751(a)(2)(C) of the Act: (1) for Giti, Sumitomo, and the other exporters listed above that have a separate rate, the cash deposit rate will be the rate established in the final results of review (except, if the rate is zero or *de minimis,* then a cash deposit rate of zero will be established for that company); (2) for previously investigated or reviewed exporters not listed in the table above that have separate rates, the cash deposit rate will continue to be the existing exporter-specific rate published for the most recently-completed segment of this proceeding; (3) 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 (*i.e.,* 76.46 percent); and (4) for all exporters of subject merchandise which are not located in China and have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-China exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping 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 the countervailing duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. 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 violation which is subject to sanction.

Notification to Interested Parties

We are issuing these final results of administrative review and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1) and 351.221(b)(5).

Dated: March 5, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Enforcement and Compliance, 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. Changes Since the *Preliminary Results*
IV. Discussion of the Issues
Comment 1: Selection of Surrogate Country
Comment 2: Surrogate Financial Statements
Comment 3: Surrogate Value (SV) for Labor
Comment 4: SVs for Electricity and Water
Comment 5: SV for Truck Freight
Comment 6: Whether To Grant an Export Subsidy Offset
Comment 7: Triangle Tyre Co., Ltd's (Triangle Tyre) No-Shipment Status
Comment 8: Whether Commerce Should Inform U.S. Customs and Border Protection (CBP) Regarding the Shipments Addressed by Prinx Chengshan (Shandong) Tire Company Ltd. (PCT)
Comment 9: Whether Commerce Should Use Giti's Reported Factoring Discount
Comment 10: Ministerial Errors for Giti
Comment 11: Differential Pricing Analysis
Comment 12: Offset for SRC's Production of Turn Up Bladders (TUB)
Comment 13: Ministerial Errors for Sumitomo
V. Recommendation

Appendix II

Separate Rate Companies

1. Anhui Jichi Tire Co., Ltd.
2. Hankook Tire China Co., Ltd.
3. Jiangsu Hankook Tire Co., Ltd.
4. Koryo International Industrial Limited
5. Mayrun Tyre (Hong Kong) Limited
6. Qingdao Keter International Co., Limited
7. Qingdao Sentury Tire Co., Ltd.; Sentury (Hong Kong) Trading Co., Limited
8. Qingdao Sunfulcess Tyre Co., Ltd.
9. Shandong Haohua Tire Co., Ltd.
10. Shandong Linglong Tyre Co., Ltd.
11. Shandong New Continent Tire Co., Ltd.
12. Shandong Province Sanli Tire Manufactured Co., Ltd.

Appendix III

Companies Found To Be Part of the China-Wide Entity

1. Aeolus Tyre Corp., Ltd.
2. Double Coin Tire Ltd.
3. Hongtyre Group Co.
4. Nankang (Zhangjiagang Free Trade Zone) Rubber Industrial Co., Ltd.
5. Qingdao Crowntyre Industries Co., Ltd.
6. Shandong Habilead Rubber Co., Ltd.
7. Shangdong Hengfeng Rubber & Plastic Co., Ltd.
8. Shangdong Hengyu Science & Technology Co., Ltd.
9. Shangdong Longyue Rubber Co., Ltd. (aka ZODO Tire Co., Ltd.)
10. Shangdong Yongfeng Tyres Co., Ltd.
11. Shanghai Tire & Rubber (Group) Ltd.
12. Tianjin Wanda Tyre Group Company, Ltd.
13. Tyrechamp Group Co., Limited
14. Wendeng Sanfeng Tyre Co., Ltd.
15. Zhongce Rubber Group Co., Ltd.

[FR Doc. 2024–05169 Filed 3–11–24; 8:45 am]

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[13] *See Non-Market Economy Assessment Notice,* 76 FR at 65694, for a full discussion of this practice.

[14] *See Order,* 80 FR at 47906.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–810]

Stainless Steel Bar From India: Continuation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the U.S. Department

of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the antidumping duty (AD) order on stainless steel bar (SS Bar) from India would likely lead to the continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing a notice of continuation of this AD order.

DATES: Applicable February 28, 2024.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg or Garry Kasparov, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1785, or (202) 482–1397, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 21, 1995, Commerce published in the **Federal Register** the AD *Order* on SS Bar from India.[1] On September 1, 2023, the ITC instituted,[2] and Commerce initiated,[3] the fifth sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its review, Commerce determined that revocation of the *Order* would likely lead to the continuation or recurrence of dumping, and therefore, notified the ITC of the magnitude of the margins of dumping rates likely to prevail should the *Order* be revoked.[4]

On February 28, 2024, the ITC published its determination, pursuant to sections 751(c) of the Act, that revocation of the *Order* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Order

The merchandise subject to the *Order* is SS Bar. SS Bar means articles of stainless steel in straight lengths that have been either hot-rolled, forged, turned, cold-drawn, cold-rolled or otherwise cold-finished, or ground, having a uniform solid cross section along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons or other convex polygons. SS Bar includes cold-finished SS Bars that are turned or ground in straight lengths, whether produced from hot-rolled bar or from straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, grooves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi-finished products, cut length flat-rolled products (*i.e.,* cut length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness, or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), wire (*i.e.,* cold-formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat-rolled products), and angles, shapes and sections.

Imports of these products are currently classifiable under subheadings 7222.11.00, 7222.19.00, 7222.20.00, 7222.30.00 of the Harmonized Tariff Schedule (HTS). Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of the *Order* is dispositive.[6]

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the *Order* would likely lead to continuation or recurrence of dumping, and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, Commerce hereby orders the continuation of the *Order.* U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the *Order* will be February 28, 2024.[7] Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year reviews of the *Order* not later than 30 days prior to fifth anniversary of the date of the last determination by the ITC.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. 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 violation which is subject to sanctions.

Notification to Interested Parties

This five-year (sunset) review and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: March 6, 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. 2024–05172 Filed 3–11–24; 8:45 am]

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[1] *See Antidumping Duty Orders: Stainless Steel Bar from Brazil, India and Japan,* 60 FR 9661 (February 21, 1995) *(Order).*

[2] *See Stainless Steel Bar from India; Institution of a Five-Year Review,* 88 FR 60486 (September 1, 2023).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 60438 (September 1, 2023) (*Initiation Notice*).

[4] *See Stainless Steel Bar from India: Final Results of the Expedited Fifth Sunset Review of the Antidumping Duty Order,* 89 FR 324 (January 3, 2024), and accompanying Issues and Decision Memorandum (IDM).

[5] *See Stainless Steel Bar from India,* 89 FR 14718 (February 28, 2024) (*ITC Final Determination*).

[6] *See Order.*

[7] *See ITC Final Determination.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD635]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Trident Seafoods Bunkhouse Dock Replacement Project, Kodiak, Alaska

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Trident Seafoods Corporation (Trident) to incidentally harass marine mammals during construction activities associated with the Bunkhouse Dock replacement project in Kodiak, Alaska.

DATES: This authorization is effective from March 1, 2024, through February 29, 2025.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-*

protection/incidental-take-authorizations-construction-activities. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On June 15, 2023, NMFS received a request from Trident for an IHA to take marine mammals incidental to vibratory and impact pile driving to replace the Bunkhouse Dock at their facility in Kodiak, Alaska. Following NMFS' review of the application, Trident submitted a revised version on September 1, 2023. The application was deemed adequate and complete on October 26, 2023. Trident's request is for take of six species of marine mammals by Level B harassment only. Neither Trident nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

There are no changes from the proposed IHA to the final IHA.

Description of Specified Activity

Overview

Trident plans to remove and replace the Bunkhouse Dock on the shore of Near Island Channel in Kodiak, Alaska. Starting in March 2024 and lasting 8 weeks, Trident will use down-the-hole (DTH) drilling and vibratory pile driving to remove existing piles and install new ones.

The Bunkhouse Dock replacement will include the removal of 100 14-inch (in), or 36-centimeter (cm) diameter timber piles, 75 14-in (36-cm) steel H-piles, and 60 16-in (41-cm) diameter steel pipe piles. Once the existing piles are removed, 26 16-in (41-cm) diameter steel pipe piles and 52 24-in (61-cm) diameter steel pipe piles would be installed to support the new pier. The installation and removal of 52 temporary 24-in (61-cm) diameter steel pipe piles would be completed to support permanent pile installation. All piles will be removed with the deadpull method with the vibratory hammer being used if the deadpull method is unsuccessful. Temporary and permanent piles will be initially installed with the vibratory hammer followed by the DTH drill to embed them to their final depth.

A further detailed description of the planned construction project is provided in the **Federal Register** notice for the proposed IHA (88 FR 88874, December 26, 2023). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specified activity. Mitigation, monitoring, and reporting measures are described in detail later in this document (please see Mitigation and Monitoring and Reporting sections).

Comments and Responses

A notice of NMFS' proposal to issue an IHA to Trident was published in the **Federal Register** on December 26, 2023 (88 FR 88874). That notice described, in detail, Trident's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. In that notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and any other aspect of the notice of proposed IHA, and requested that interested persons submit relevant information, suggestions, and comments. During the 30-day public comment period, NMFS did not receive any public comments.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 1 lists all species or stocks for which take is expected and authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' Alaska SARs (Young *et al.,* 2023), including the draft 2023 SARs. All values presented in table 1 are the most recent available at the time of publication and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*.

TABLE 1—MARINE MAMMAL SPECIES [1] LIKELY TO OCCUR NEAR THE PROJECT AREA THAT MAY BE TAKEN BY TRIDENT'S ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI *
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
Family Balaenopteridae (rorquals):						
Humpback Whale	*Megaptera novaeangliae*	Hawai'i [4]	-, -, N	11,278 (0.56, 7,265, 2020).	127	27.09
		Mexico-North Pacific [4]	T, D, Y	3,477 (0.101, 3,185, 2018).	43	22
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Killer Whale	*Orcinus orca*	Eastern North Pacific Alaska Resident [5].	-, -, N	1,920 (N/A, 1,920, 2019)	19	1.3
		Eastern North Pacific Gulf of Alaska, Aleutian Islands and Bering Sea Transient [6].	-, -, N	587 (N/A, 587, 2012)	5.9	0.8
Family Phocoenidae (porpoises):						
Dall's Porpoise	*Phocoenoides dalli*	Alaska [7]	-, -, N	UND (UND, UND, 2015)	UND	37
Harbor Porpoise	*Phocoena phocoena*	Gulf of Alaska	-, -, Y	31,046 (0.21, N/A, 1998)	UND	72
Order Carnivora—Pinnipedia						
Family Otariidae (eared seals and sea lions):						
Steller Sea Lion	*Eumetopias jubatus*	Western [8]	E, D, Y	49,837 (N/A, 49,837, 2022).	299	267
Family Phocidae (earless seals):						
Harbor Seal	*Phoca vitulina*	South Kodiak	-, -, N	26,448 (N/A, 22,351, 2017).	939	127

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies*).

[2] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region*. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

* These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

[4] New SAR in 2022 following North Pacific humpback whale stock structure changes.

[5] Abundance estimates are based upon data collected more than 8 years ago and, therefore, current estimates are considered unknown.

[6] N_{est} is based upon counts of individuals identified from photo identification catalogs.

[7] The best available abundance estimate is likely an underestimate for the entire stock because it is based upon a survey that covered only a small portion of the stock's range.

[8] N_{est} is best estimate of counts, which have not been corrected for animals at sea during abundance surveys.

As indicated above, all six species (with eight managed stocks) in table 1 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. All species that could potentially occur in the project area are included in table 5 of the IHA application. While gray whales, North Pacific right whales, minke whales, fin whales, Cuvier's beaked whales, sperm whales, Pacific white-sided dolphins, and northern fur seals in the area, the temporal and/or spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. These species are all considered to be rare (no sightings in recent years) within the project area. Take of these species has not been requested nor authorized and these species are not considered further in this document.

A detailed description of the species likely to be affected by Trident's construction project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (88 FR 88874, December 26, 2023); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to the NMFS website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct

measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65-dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from Trident's pile driving activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the project area. The notice of the proposed IHA (88 FR 88874, December 26, 2023) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from Trident's pile driving activities on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of the proposed IHA (88 FR 88874, December 26, 2023).

Estimated Take

This section provides an estimate of the number of incidental takes authorized through the IHA, which will inform both NMFS' consideration of ''small numbers,'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which: (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to pile driving activities. Based on the nature of the activity, Level A harassment is neither anticipated nor authorized.

As described previously, no serious injury or mortality is anticipated or authorized for this activity. Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and is authorized.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the authorized take numbers.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021; Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-

squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μPa)) for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

Trident's planned activity includes the use of continuous (vibratory pile driving) sources, and therefore the RMS SPL threshold of 120 dB re 1 μPa is applicable. DTH drilling has both continuous and intermittent (impulsive) components as discussed in the *Description of Sound Sources* section above. When evaluating Level B harassment, NMFS recommends treating DTH as a continuous source and applying the RMS SPL thresholds of 120 dB re 1 μPa.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0; Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). Trident's planned activity includes the use of non-impulsive (vibratory pile driving) sources. As described above, DTH includes both impulsive and non-impulsive characteristics. When evaluating Level A harassment, NMFS recommends treating DTH as an impulsive source.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance*.

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-pk,flat}}$: 219 dB; $L_{E,p,LF,24h}$: 183 dB	*Cell 2:* $L_{E,p,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{p,0\text{-pk,flat}}$: 230 dB; $L_{E,p,MF,24h}$: 185 dB	*Cell 4:* $L_{E,p,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{p,0\text{-pk,flat}}$: 202 dB; $L_{E,p,HF,24h}$: 155 dB	*Cell 6:* $L_{E,p,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{p,0\text{-pk,flat}}$: 218 dB; $L_{E,p,PW,24h}$: 185 dB	*Cell 8:* $L_{E,p,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{p,0\text{-pk,flat}}$: 232 dB; $L_{E,p,OW,24h}$: 203 dB	*Cell 10:* $L_{E,p,OW,24h}$: 219 dB.

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0\text{-pk}}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μPa^2s. In this table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.,* 7 Hz to 160 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the planned project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* vibratory pile driving and removal, DTH drilling). The maximum (underwater) area ensonified above the thresholds for behavioral harassment referenced above is 125 km^2 (48.26 mi^2), that would be truncated by land masses that would obstruct underwater sound transmission and would extend into Near Island Channel and St. Paul Harbor (see figure 5 in Trident's application). Additionally, vessel traffic and other commercial and industrial activities in the project area may contribute to elevated background noise levels which may mask sounds produced by the project.

Transmission loss (*TL*) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. *TL* parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater *TL* is:

$$TL = B \times \mathrm{Log}_{10}\,(R_1/R_2),$$

Where:

TL = transmission loss in dB,
B = transmission loss coefficient,
R_1 = the distance of the modeled SPL from the driven pile, and
R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6-dB reduction in sound level for each doubling of distance from the source (20×log[range]). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source (10×log[range]). A practical

spreading value of 15 is often used under conditions, such as the project site, where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions. Practical spreading loss is assumed here.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, the applicant and NMFS used acoustic monitoring data from other locations to develop proxy source levels for the various pile types, sizes and methods. The project includes vibratory and DTH pile installation of steel pipe piles and vibratory removal of steel pipe piles, steel H-piles, and timber piles. Source levels for each pile size and driving method are presented in table 4.

TABLE 4—PROXY SOUND SOURCE LEVELS FOR PILE SIZES AND DRIVING METHODS

Pile type	Installation or removal	RMS SPL (re 1 μPa)	SEL (re 1 μPa²-sec)	Source
Vibratory Pile Driving				
14-in timber pile	Removal	162	NA	Caltrans, 2020.
14-in H-pile	Removal	150		Caltrans, 2020.
16-in steel pile	Installation	161		NAVFAC, 2015.
16-in steel pile	Removal			NAVFAC, 2015.
24-in steel pile	Installation and Removal			NAVFAC, 2015.
DTH Drilling [1]				
16-in steel pile	Installation	162	141	Heyvaert & Reyff, 2021; Guan & Miner, 2020.
24-in steel pile	Installation		154	Heyvaert & Reyff, 2021.

[1] Sound source levels for DTH were adjusted by −5 dB to reflect the use of the bubble curtain.

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Inputs used in the optional User Spreadsheet tool, and the resulting estimated isopleths, are reported below.

TABLE 5—NMFS USER SPREADSHEET INPUTS

Pile size and type	Spreadsheet tab used	Weighting factor adjustment (kHz)	Transmission loss coefficient	Number of piles per day	Activity duration (minutes)
14-in timber pile vibratory removal	A.1 Vibratory pile driving	2.5	15	25	2
14-in steel H-pile vibratory removal	A.1 Vibratory pile driving	2.5	15	20	2
16-in steel pipe pile vibratory removal	A.1 Vibratory pile driving	2.5	15	20	2
16-in steel pipe pile vibratory installation	A.1 Vibratory pile driving	2.5	15	5	2
24-in steel pipe pile vibratory installation (temporary).	A.1 Vibratory pile driving	2.5	15	6	2
24-in steel pipe pile vibratory removal (temporary).	A.1 Vibratory pile driving	2.5	15	8	2
24-in steel pipe pile vibratory installation	A.1 Vibratory pile driving	2.5	15	4	2
16-in steel pipe pile DTH installation	E.2 DTH pile driving	2	15	6	45
24-in steel pipe pile DTH installation (temporary).	E.2 DTH pile driving	2	15	6	30
24-in steel pipe pile DTH installation	E.2 DTH pile driving	2	15	4	60

TABLE 6—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Otariids	Phocids	
14-in timber pile vibratory removal	7.1	0.6	10.4	4.3	0.3	6,310
14-in steel H-pile vibratory removal	1	0.1	1.4	0.6	0	1,000
16-in steel pipe pile vibratory removal	5.2	0.5	7.7	3.2	0.2	5,415

TABLE 6—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS—Continued

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Otariids	Phocids	
16-in steel pipe pile vibratory installation	2.1	0.2	3.1	1.3	0.1	.....
24-in steel pipe pile vibratory installation (temporary)	2.3	0.2	3.5	1.4	0.1	.....
24-in steel pipe pile vibratory removal (temporary)	2.8	0.3	4.2	1.7	0.1	.....
24-in steel pipe pile vibratory installation	1.8	0.2	2.6	1.1	0.1	.....
16-in steel pipe pile DTH installation	47	1.7	56	1.8	25.2	6,310
24-in steel pipe pile DTH installation (temporary)	264.1	9.4	314.5	10.3	141.3	.....
24-in steel pipe pile DTH installation	319.9	11.4	381	12.5	171.2	.....

Marine Mammal Occurrence and Take Estimation

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

When available, peer-reviewed scientific publications were used to estimate marine mammal abundance in the project area. Data from monitoring reports from projects on the Kodiak Ferry Terminal were used as well as reports from other projects in Kodiak, Alaska.

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and is authorized. Tables for each species are presented to show the calculation of take during the project. Both density and occurrence data was considered in incidental take estimations. Density data were used when there was no occurrence data available, or when occurrence and density data were similar. The take calculations for this project are:

Incidental take estimate = group size × days of pile driving activity,

Or

Incidental take estimate = (Activity Level B harassment area [km^2] × estimated density [individuals/km^2]) × days of pile driving activity

Humpback Whale

Humpback whales are present in Kodiak year-round with peaks in the spring and fall. They are considered common in the project area, meaning there are multiple sightings every month, so they could occur daily in the project's action. In the project area humpback whales are expected to occur at a density of 0.093 individuals per square kilometer area (Halpin *et al.,* 2009). Therefore, using the equation given above, the total number of Level B harassment takes for humpback whales would be 14. In the action area it is estimated that the majority of whales (89 percent) will be from the Hawai'i distinct population segment (DPS), 11 percent will be from the Mexico DPS, and 1 percent will be from the endangered western North Pacific DPS (Wade, 2021; Muto *et al.,* 2022). Therefore 13 takes are assumed to be from the Hawai'i DPS and 1 take from the Mexico DPS.

The largest Level A harassment zone for humpback whales extends 319.9 m from the noise source (table 6). All construction work would be shut down prior to a humpback whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the infrequent occurrence of humpback whales in the project area and shutdown requirements, no take by Level A harassment is anticipated or authorized for humpback whales.

Killer Whale

Killer whales are present in Kodiak year-round and are considered common in the project area, meaning there are multiple sightings every month, so they could occur daily in the project's action. A single group of up to six killer whales are expected to occur in the project area daily (Halpin *et al.,* 2009). Therefore, using the equation given above, the total number of Level B harassment takes for killer whales would be 330. In the action area it is estimated that the majority of killer whales (80 percent) will be from the Alaska resident stock and 20 percent will be from the Gulf of Alaska/Aleutian Islands/Bering Sea transient stock (Muto *et al.,* 2022). Therefore 264 takes are assumed to be from the Alaska resident stock and 66 takes from the Gulf of Alaska/Aleutian Islands/Bering Sea transient stock.

The largest Level A harassment zone for killer whales extends 11.4 m from the noise source (table 6). All construction work would be shut down prior to a killer whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the small size of the Level A harassment zone and shutdown requirements, no take by Level A harassment is anticipated or authorized for killer whale.

Harbor Porpoise

Harbor porpoises are present in Kodiak year-round and are occur frequently in the project area, meaning there are multiple sightings every year, so they could occur monthly in the project's action. In the project area harbor porpoises are expected to occur at a density of 0.4547 individuals per square kilometer area (Marine Geospatial Ecology Lab, 2021). Therefore, using the equation given above, the total number of Level B harassment takes for harbor porpoises would be 65.

The largest Level A harassment zone for harbor porpoise extends 381 m from the noise source (table 6). All construction work would be shut down prior to a harbor porpoise entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the relatively low anticipated exposure in the project area and the anticipated effectiveness of the shutdown requirements, no take by Level A harassment is anticipated or authorized for harbor porpoise.

Dall's Porpoise

Dall's porpoises are present in Kodiak year-round and are occur frequently in the project area, meaning there are multiple sightings every year, so they could occur monthly in the project's action. In the project area Dall's porpoises are expected to occur at a density of 0.218 individuals per square kilometer (Marine Geospatial Ecology Lab, 2021). Therefore, using the equation given above, the total number of Level B harassment takes for Dall's porpoise would be 31.

The largest Level A harassment zone for Dall's porpoise extends 381 m from the noise source (table 6). All construction work would be shut down prior to a Dall's porpoise entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the relatively low anticipated exposure in the project area

and the anticipated effectiveness of the shutdown requirements, no take by Level A harassment is anticipated or authorized for Dall's porpoise.

Harbor Seal

Harbor seals are present in Kodiak year-round and are considered common in the project area, meaning there are multiple sightings every month, so they could occur daily in the project's action. In the project area Dall's porpoises are expected to occur at a density of 0.1689 individuals per square kilometer (Marine Geospatial Ecology Lab, 2021). Therefore, using the equation given above, the total number of Level B harassment takes for harbor seals would be 24.

The largest Level A harassment zone for harbor seals extends 171.2 m from the noise source (table 6). All construction work would be shut down prior to a harbor seal entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the relatively low anticipated exposure in the project area and the anticipated effectiveness of the shutdown requirements, no take by Level A harassment is anticipated or authorized for harbor seals.

Steller Sea Lion

Steller sea lions are present in Kodiak year-round and are considered common in the project area, meaning there are multiple sightings every month, so they could occur daily in the project's action. During construction at the Kodiak Ferry Terminal (82 FR 10894, February 26, 2017) Steller sea lions were encountered daily during construction. Up to 40 Steller sea lions are expected to occur in the project area daily (Marine Geospatial Ecology Lab, 2021). Therefore, using the equation given above, the total number of Level B harassment takes for Steller sea lions would be 2,200.

The largest Level A harassment zone for harbor seals extends 12.5 m from the noise source (table 6). All construction work would be shut down prior to a Steller sea lion entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the small Level A harassment isopleth and shutdown requirements, no take by Level A harassment is anticipated or authorized for Steller sea lions.

TABLE 7—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance [a]	Level A harassment	Level B harassment	Total take	Take as percentage of stock
Humpback whale	Hawai'i	11,278	0	13	13	0.1
	Mexico-North Pacific	3,477	0	1	1	0.03
Killer Whale	Alaska Resident	1,920	0	264	264	13.8
	Gulf of Alaska/Aleutian Islands/Bering Sea Transient.	587	0	66	66	11.2
Harbor porpoise	Gulf of Alaska	31,946	0	65	65	0.08
Dall's porpoise	Alaska	13,110	0	31	31	0.24
Steller sea lion	Western U.S	49,837	0	2,200	2,200	4.4
Harbor seal	South Kodiak Island	26,448	0	24	24	0.09

[a] Stock abundance is N_{best} according to NMFS 2022 and draft 2023 Stock Assessment Reports.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

In addition to the measures described later in this section, Trident would employ the following standard mitigation measures:

- At the start of each day, the contractor(s) would hold a briefing with the Lead Protected Species Observer (PSO) to outline the activities planned for that day.
- If poor weather conditions restrict the PSO's ability to make observations within the Level A harassment zone of pile driving (*e.g.,* if there is excessive wind or fog), pile installation and removal would be halted.

The following measures would apply to Trident's mitigation requirements:

Shutdown and Monitoring Zones

Trident must establish shutdown zones and Level B monitoring zones for all pile driving activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine animal (or in anticipation of an animal entering the defined area). Shutdown zones are based on the largest Level A harassment zone for each pile size/type and driving method, and behavioral monitoring zones are meant to encompass Level B harassment zones for each pile size/type and driving method, as shown in table 8. A minimum shutdown zone of 10 m would be required for all in-water

construction activities to avoid physical interaction with marine mammals. Marine mammal monitoring will be conducted during all pile driving activities to ensure that marine mammals do not enter Level A shutdown zones. Shutdown zones for each activity type are shown in table 8.

Prior to pile driving, shutdown zones and monitoring zones will be established based on zones represented in table 8. Observers will survey the shutdown zones for at least 30 minutes before pile driving activities start. If marine mammals are found within the shutdown zone, pile driving will be delayed until the animal has moved out of the shutdown zone, either verified by an observer or by waiting until 15 minutes has elapsed without a sighting. If a marine mammal approaches or enters the shutdown zone during pile driving, the activity will be halted. Pile driving may resume after the animal has moved out of and is moving away from the shutdown zone or after at least 15 minutes has passed since the last observation of the animal.

All marine mammals would be monitored in the Level B harassment zones and throughout the area as far as visual monitoring can take place. If a marine mammal enters the Level B harassment zone, in-water activities would continue and PSOs would document the animal's presence within the estimated harassment zone.

If a species for which authorization has not been granted, or a species which has been granted but the authorized takes are met, is observed approaching or within the Level B harassment zone, pile driving activities will be shut down immediately. Activities will not resume until the animal has been confirmed to have left the area or 15 minutes has elapsed with no sighting of the animal.

TABLE 8—SHUTDOWN AND LEVEL B HARASSMENT ZONES BY ACTIVITY

Pile size, type, and method	Minimum shutdown zone					Level B harassment zone
	Low-frequency	Mid-frequency	High-frequency	Phocid	Otariid	
Barge movements, pile positioning	10	10	10	10	10	10
14-in timber pile vibratory removal	10	10	15	10	10	6,310
14-in steel H-pile vibratory removal	10	10	10	10	10	1,000
16-in steel pipe pile vibratory removal	10	10	10	10	10	5,415
16-in steel pipe pile vibratory installation	10	10	10	10	10	5,415
24-in steel pipe pile vibratory installation (temporary)	10	10	10	10	10	5,415
24-in steel pipe pile vibratory removal (temporary)	10	10	10	10	10	5,415
24-in steel pipe pile vibratory installation	10	10	10	10	10	5,415
16-in steel pipe pile DTH installation	50	10	60	30	10	6,310
24-in steel pipe pile DTH installation (temporary)	265	10	315	145	15	6,310
24-in steel pipe pile DTH installation	320	15	385	175	15	6,310

Protected Species Observers

The placement of PSOs during all pile driving activities (described in the Monitoring and Reporting section) would ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone would not be visible (*e.g.,* fog, heavy rain), pile driving would be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

PSOs would monitor the full shutdown zones and as much of the Level B harassment zones as possible. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring enables observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre- and Post-Activity Monitoring

Monitoring must take place from 30 minutes prior to initiation of pile driving activities (*i.e.,* pre-clearance monitoring) through 30 minutes post-completion of pile driving. Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs would observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone would be considered cleared when a marine mammal has not been observed within the zone for a 30-minute period. If a marine mammal is observed within the shutdown zones, pile driving activity would be delayed or halted. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones would commence. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

Bubble Curtain

A bubble curtain must be employed during all impact DTH activities to interrupt the acoustic pressure and reduce impact on marine mammals. The bubble curtain must distribute air bubbles around 100 percent of the piling circumference for the full depth of the water column. The lowest bubble ring must be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring must ensure 100 percent substrate contact. No parts of the ring or other objects may prevent full substrate contact. Air flow to the bubblers must be balanced around the circumference of the pile.

Based on our evaluation of the applicant's planned measures, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing

the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

Visual Monitoring

Monitoring shall be conducted by NMFS-approved observers in accordance with the monitoring plan and section 5 of the IHA. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator. Observer training must be provided prior to project start, and shall include instruction on species identification (sufficient to distinguish the species in the project area), description and categorization of observed behaviors and interpretation of behaviors that may be construed as being reactions to the specified activity, proper completion of data forms, and other basic components of biological monitoring, including tracking of observed animals or groups of animals such that repeat sound exposures may be attributed to individuals (to the extent possible).

Monitoring would be conducted 30 minutes before, during, and 30 minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving/removal activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Between one and five PSOs will be on duty depending on the size of the monitoring zone. Locations from which PSOs would be able to monitor for marine mammals are readily available from publicly accessible shoreside areas at the Near Island Channel and surrounding waters. Monitoring locations would be selected by the Contractor during pre-construction. PSOs would monitor for marine mammals entering the Level B harassment zones; the position(s) may vary based on construction activity and location of piles or equipment.

PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring would be conducted by qualified observers, who would be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator via a radio. Trident would adhere to the following observer qualifications:

(i) Independent observers (*i.e.,* not construction personnel) are required;

(ii) One PSO would be designated as the lead PSO or monitoring coordinator and that observer must have prior experience working as an observer;

(iii) Other observers may substitute education (degree in biological science or related field) or training for experience; and

(iv) Trident must submit observer Curricula Vitae for approval by NMFS.

Additional standard observer qualifications include:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Data Collection

PSOs would use approved data forms to record the following information:

- Dates and times (beginning and end) of all marine mammal monitoring.
- PSO locations during marine mammal monitoring.

Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed and by what method (*i.e.,* vibratory or DTH).

- Weather parameters and water conditions.
- The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting.
- Distance and bearings of each marine mammal observed to the pile being driven or removed.
- Description of marine mammal behavior patterns, including direction of travel.
- Age and sex class, if possible, of all marine mammals observed.
- Detailed information about implementation of any mitigation triggered (such as shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal if any.

Reporting

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of

pile driving and removal activities. It would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring.
- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.,* vibratory driving) and the total equipment duration for cutting for each pile.
- PSO locations during marine mammal monitoring.
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information: name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; time of sighting; identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); estimated number of animals (min/max/best estimate); estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); animal's closest point of approach and estimated time spent within the harassment zone; description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the harassment zones, by species.
- Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report would constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA (if issued), such as an injury, serious injury or mortality, Trident would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.,* Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Trident to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Trident would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Trident discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), Trident would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Trident to determine whether modifications in the activities are appropriate.

In the event that Trident discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Trident would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. Trident would provide photographs, video footage (if available), or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to all the species listed in table 1, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

Pile driving and removal activities associated with the project as outlined

previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment from underwater sounds generated from pile driving and removal. Level A harassment is extremely unlikely given the small size of the Level A harassment isopleths and the required mitigation measures designed to minimize the possibility of injury to marine mammals (see Mitigation section). No mortality is anticipated given the nature of the activity. Pile installation and removal activities are likely to result in the Level B harassment of marine mammals that move into the ensonified zone, primarily in the form of disturbance or displacement of marine mammals. Take would occur within a limited, confined area of each stock's range. Level B harassment would be reduced to the level of least practicable adverse impact through use of mitigation measures described herein. Further, the amount of take authorized is small when compared to stock abundance.

Based on reports in the literature as well as monitoring from other similar activities, behavioral disturbance (*i.e.,* level B harassment) would likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006; HDR, Inc., 2012; Lerma, 2014; ABR, 2016). Most likely for pile driving, individuals would simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in Alaska, which have taken place with no observed severe responses of any individuals or known long-term adverse consequences. Level B harassment would be reduced to the level of least practicable adverse impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring. While vibratory driving associated with the project may produce sound at distances of many kilometers from the project site, thus overlapping with some likely less-disturbed habitat, the project site itself is located in a busy harbor and the majority of sound fields produced by the specified activities are close to the harbor. Animals disturbed by project sound would be expected to avoid the area and use nearby higher-quality habitats.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish or invertebrates to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities, the relatively small area of the habitat that may be affected, and the availability of nearby habitat of similar or higher value, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

The waters around Kodiak Island are part of the Alaska humpback whale feeding Biologically Important Area (BIA; Ferguson *et al.,* 2015). Humpback whales are present around Kodiak, although the majority of sightings have occurred outside of Near Island Channel. The area of the BIA that may be affected by the planned project is small relative to the overall area of the BIA. The humpback whale feeding BIA is active between May and November while the planned project is scheduled to occur between March and June, resulting in only 2 months of overlap. Additionally, pile driving associated with the project is expected to take only 55 days, further reducing the temporal overlap with the BIA. Therefore, the planned project is not expected to have significant adverse effects on the foraging of Alaska humpback whale. No areas of specific biological importance (*e.g.,* ESA critical habitat, other BIAs, or other areas) for any other species are known to co-occur with the project area.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury, mortality, or Level A harassment is anticipated or authorized;
- The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that would not result in fitness impacts to individuals;
- The ensonified areas from the project are very small relative to the overall habitat ranges of all species and stocks;
- The lack of anticipated significant or long-term negative effects to marine mammal habitat or any other areas of known biological importance; and
- The mitigation measures are expected to reduce the effects of the specified activity to the level of least practicable adverse impact.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the planned activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 7 demonstrates the number of animals that could be exposed to received noise levels that could cause Level B harassment for the work in Kodiak, Alaska. Our analysis shows that less than 14 percent of each affected stock could be taken by harassment. The numbers of animals authorized to be taken for these stocks would be considered small relative to the relevant stock's abundances, even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Based on the analysis contained herein of the planned activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

In the Kodiak area sea lions and harbor seals are available for subsistence harvest under the MMPA. Limited subsistence harvests of marine mammals outside of Near Island Channel has occurred in the past, with the most recent recorded/documented harvests of marine mammals in Kodiak in 2011. The planned activity will take place in Near Island Channel, and no activities overlap with current subsistence hunting areas; therefore, there are no relevant subsistence uses of marine mammals adversely impacted by this action. The planned project is not likely to adversely impact the availability of any marine mammal species or stocks that are commonly used for subsistence purposes or to impact subsistence harvest of marine mammals in the region.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from Trident's planned activities.

Endangered Species Act

There are two marine mammal species (Mexico DPS humpback whale and western DPS Steller sea lion) with confirmed occurrence in the project area that are listed as endangered under the ESA. The NMFS Alaska Regional Office issued a Biological Opinion under section 7 of the ESA, on the issuance of an IHA to Trident under section 101(a)(5)(D) of the MMPA by the NMFS Office of Protected Resources. The Biological Opinion concluded that the proposed action is not likely to jeopardize the continued existence of Mexico DPS humpback whales or western DPS Steller sea lions, and is not likely to destroy or adversely modify Mexico DPS humpback whale and western DPS Steller sea lion critical habitat.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must evaluate our proposed action (*i.e.,* the issuance of an IHA) and alternatives with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to Trident for the potential harassment of small numbers of six marine mammal species incidental to the Bunkhouse Dock replacement project in Kodiak, Alaska, that includes the previously explained mitigation, monitoring and reporting requirements.

Dated: March 6, 2024.

Catherin Marzin,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–05163 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of U.S. Virgin Islands Coastal Management Program; Notice of Public Meetings; Request for Comments

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of public meetings and opportunity to comment.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office for Coastal Management, will hold three in-person public meetings to solicit input on the performance evaluation of the U.S. Virgin Islands Coastal Management Program. NOAA also invites the public to submit written comments.

DATES: NOAA will hold in-person public meetings on Tuesday, May 14, 2024, at 5 p.m. on St. Thomas; on Wednesday, May 15, 2024, at 5 p.m. on St. John; and on Thursday, May 16, 2024, at 5 p.m. on St. Croix. NOAA may close the meetings 10 minutes after the conclusion of public testimony and after responding to any clarifying questions from participants. NOAA will consider all relevant written comments received by Friday, May 24, 2024.

ADDRESSES: Comments may be submitted by one of the following methods:

- *In-Person Public Meeting:* Provide oral comments during an in-person public meeting.
  - *St. Thomas:* Tuesday, May 14, 2024, at 5 p.m. at Department of Planning and Natural Resources Offices, 4611 Tutu Park Mall, Suite 300, St. Thomas, U.S. Virgin Islands 00802;
  - *St. John:* Wednesday, May 15, 2024, at 5 p.m. at Legislature of the U.S. Virgin Islands St. John Annex, 1D Great Cruz Bay Road, Cruz Bay, St. John, U.S. Virgin Islands 00830; or
  - *St. Croix:* Thursday, May 16, 2024, at 5 p.m. at University of the Virgin Islands Great Hall, Albert A. Sheen Campus, St. Croix, U.S. Virgin Islands.
- *Email:* Send written comments to Michael Migliori, Evaluator, NOAA Office for Coastal Management, at *Michael.Migliori@noaa.gov.* Include ''Comments on Performance Evaluation of the U.S. Virgin Islands Coastal Management Program'' in the subject line of the message.

NOAA will accept anonymous comments; however, the written comments NOAA receives are considered part of the public record, and the entirety of the comment, including the name of the commenter, email address, attachments, and other supporting materials, will be publicly accessible. Sensitive personally identifiable information, such as account numbers and Social Security numbers, should not be included with the comment. Comments that are not related to the performance evaluation of the U.S. Virgin Islands Coastal Management Program or that contain profanity, vulgarity, threats, or other inappropriate language will not be considered.

FOR FURTHER INFORMATION CONTACT: Michael Migliori, Evaluator, NOAA Office for Coastal Management, by email at *Michael.Migliori@noaa.gov* or by phone at (443) 332–8936. Copies of the previous evaluation findings and Assessment and Strategies may be viewed and downloaded at *http://coast.noaa.gov/czm/evaluations/*. A copy of the evaluation notification letter and most recent progress report may be obtained upon request by contacting Michael Migliori.

SUPPLEMENTARY INFORMATION: Section 312 of the Coastal Zone Management Act (CZMA) requires NOAA to conduct periodic evaluations of federally approved coastal management programs. The evaluation process includes holding one or more public meetings, considering public comments, and consulting with interested Federal, State, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the territory of the U.S. Virgin Islands has met the national objectives, adhered to the management program approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is complete, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the final evaluation findings.

(Authority: 16 U.S.C. 1458)

Keelin Kuipers,

Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2024–05136 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD765]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Halibut and Sablefish Individual Fishing Quota Committee (IFQ Committee) will meet via web conference.

DATES: The meeting will be held on Thursday, March 28, 2024, from 9 a.m. to 11 a.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/3037.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Suite 400, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Anna Henry, Council staff; phone: (907) 271–2809; email: *anna.henry@noaa.gov.* For technical support, please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Thursday, March 28, 2024

The IFQ Committee agenda will include: (a) review and provide recommendations on Area 4 vessel cap initial review analysis; and (b) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3037* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/3037.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/3037.*

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

Dated: March 6, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–05145 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD778]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint hybrid meeting of its Scallop Committee and Habitat Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, March 27, 2024, at 9 a.m.

ADDRESSES:

Meeting address: This meeting will be held at Hotel Providence, 139 Matheson Street, Providence, RI 02903; telephone: (401) 490–8000.

Webinar registration URL information: https://attendee.gotowebinar.com/register/7856656431323045470.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Ph.D., Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Habitat and Scallop Committees will meet jointly to discuss Scallop and Habitat Plan Development Team analyses of four concept areas for potential scallop access on the Northern Edge of Georges Bank. The Habitat and Scallop Advisory Panels will provide recommendations to their respective committees on considerations for development of management alternatives. The Committees will develop guidance to the Council about development of management alternatives, particularly spatial alternatives for access area configuration. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy

of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Ph.D., Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: March 6, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–05140 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD649]

Pacific Fishery Management Council; Public Meetings and Hearings

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

ACTION: Notice of opportunities to provide public comments.

SUMMARY: The Pacific Fishery Management Council (Council) has begun its annual preseason process to develop regulations to manage the 2024 ocean salmon fisheries off the U.S. West Coast. This notice informs the public of opportunities to provide oral and written comments on the development of the regulations.

DATES: Comments received orally, electronically, or in hard copy by 5 p.m. Pacific Time, March 31, 2024, will be considered in the Council's final recommendation for the 2024 regulations. Dates when comments may be made at public hearings are provided under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Documents will be available from the Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384, and will be posted on the Council's website at *https://www.pcouncil.org.* You may submit written comments by any one of the following methods:

- *Council e-Portal:* Written comments must be submitted electronically to Mr. Marc Gorelnik, Chair, Pacific Fishery Management Council, via the Council's e-Portal by visiting *https://pfmc.psmfc.org.*
- *Federal e-Rulemaking Portal:* Electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2023–0001 in the Search box. Click on the ''Comment'' tab, complete the required fields, and enter or attach your comments. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS and the Council will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Ms. Robin Ehlke, Pacific Fishery Management Council, telephone: 503–820–2280; *email: robin.ehlke@noaa.gov.* For information on submitting comments via the Federal e-Rulemaking portal, contact Shannon Penna, NMFS West Coast Region, telephone: 562–980–4239; email: *shannon.penna@noaa.gov.*

SUPPLEMENTARY INFORMATION: On February 13, 2024, the Council announced the schedule of reports, public meetings, and hearings for the development of annual regulations for the ocean salmon fisheries that start May 16, 2024 and continue through May 15, 2025, which we refer to as the 2024 management measures (89 FR 10042; *https://www.pcouncil.org*)). The Council will adopt alternatives for 2024 ocean salmon fisheries management at its meetings to be held in person March 5–11, 2024 in Fresno, CA. Details of this meeting, including opportunities to provide public testimony in-person or virtually are available on the Council's website (*https://www.pcouncil.org*). On March 22, 2024, ''Preseason Report II—Proposed Alternatives and Environmental Assessment Part 2 for 2024 Ocean Salmon Fishery Regulations'' is scheduled to be posted on the Council's website at *https://www.pcouncil.org.* The report will include a description of the salmon management alternatives to be considered and a summary of their biological and economic impacts.

Public hearings will be held to receive oral comments on the proposed ocean salmon fishery management alternatives adopted by the Council. All public hearings begin at 7 p.m. Standard Time. Public hearings focusing on Washington and California salmon fisheries will occur simultaneously in-person on March 25, 2024. The public hearing for Oregon will occur virtually on March 26, 2024. These public hearings are tentatively scheduled to occur in person, in the cities of Westport, Washington; Coos Bay, Oregon; and Santa Rosa, California. Actual hearing venues and instructions for joining online hearings will be posted on the Council's website (*https://www.pcouncil.org*) in advance of the hearing dates. A summary of oral comments received at the hearings will be provided to the Council at its April meeting.

Comments on the alternatives the Council adopts at its March 2024 meeting, and described in its Preseason Report II, may be submitted (1) in writing or electronically as described under **ADDRESSES**, (2) orally (in-person) at a public hearing, (3) orally (online or in-person) or in writing at the Council meeting held on March 5–11, 2024, or orally (online or in-person) at the Council meeting held on April 6–11, 2024, which is scheduled to occur in person, in Seattle, Washington. Details of these meetings will be available on the Council's website (*https://www.pcouncil.org*) and will be published in the **Federal Register**. Written and electronically submitted comments must be received prior to the April 2024 Council meeting in order to be included in the briefing book for the Council's April meeting, where they will be considered in the adoption of the Council's final recommendation for the 2024 salmon fishery regulations. All comments received accordingly will be reviewed and considered by the Pacific Council and NMFS.

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

Dated: March 6, 2024.

Everett Wayne Baxter,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–05201 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD794]

South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of the Snapper Grouper Advisory Panel (AP) in Charleston, SC.

DATES: The Snapper Grouper AP will meet on March 26, 2024, from 1 p.m. until 5 p.m.; March 27, 2024, from 8:30 a.m. until 5 p.m.; and on March 28, 2024, from 8:30 a.m. until 12 p.m.

ADDRESSES: *Meeting address:* The meeting will be held at the Town & Country Inn and Suites, 2008 Savannah Highway, Charleston, SC 29407; telephone: (843) 334–6660.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; telephone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including the agenda, overview, briefing book materials, and an online public comment form will be posted on the Council's website at: *https://safmc.net/advisory-panel-meetings/* two weeks prior to the meeting. The meeting is open to the public and available via webinar as it occurs. The webinar registration link will be available from the Council's website. Public comment will also be taken during the meeting.

The agenda for the Snapper Grouper AP meeting includes: Development of a Fishery Performance Report for hogfish; updates on Council discussions pertaining to federal commercial permits and limited access to the for-hire component of South Atlantic fisheries; and an update on the Snapper Grouper Management Strategy Evaluation. The AP will also receive updates on the following amendments to the Snapper Grouper Fishery Management Plan (FMP) for the South Atlantic currently under development: Amendment 55 (scamp and yellowmouth grouper), Regulatory Amendment 36 (gag, black grouper, and black sea bass on-demand pot gear), and Amendment 56 (black sea bass assessment response).

AP members will also receive updates on additional ongoing amendments to the Snapper Grouper FMP and other Council programs and initiatives. The AP will provide input and recommendations on agenda items for the Council's consideration and address other items as needed.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: March 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–05204 Filed 3–11–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee for Strategic Environmental Research and Development Program (SERDP) Scientific Advisory Board (SAB); Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)), Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the SERDP SAB will take place.

DATES: SERDP SAB will hold a meeting open to the public. Thursday, March 21, 2024 from 9:00 a.m. to 12:30 p.m. (EST).

ADDRESSES: The meeting will be accessible by videoconference. Information for accessing the videoconference is provided in **SUPPLEMENTARY INFORMATION**, ''Meeting Accessibility''.

FOR FURTHER INFORMATION CONTACT: Dr. Kimberly Spangler, 703–571–2477 (voice), *kimberly.y.spangler.civ@mail.mil* (email). Mailing address is SERDP Office, 3500 Defense Pentagon, RM 5C646, Washington, DC 20301–3500. Website: *https://serdp-estcp.org/about.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Strategic Environmental Research and Development Program Scientific Advisory Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its March 21, 2024 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act (FACA)''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available on *https://serdp-estcp.org/about.*

Purpose of the Meeting: The purpose of the meeting is for the SERDP SAB to make recommendations regarding technologies, research, projects, programs, activities, and, if appropriate, funding within the scope of SERDP Fiscal Year (FY) 2024.

Agenda: Thursday, March 21, 2024, from 9:00 a.m. to 12:30 p.m.—Convene, Introductions, Program Overview Briefings, Project Briefings and Voting on FY 2024 Recommendations, Meet the SAB, Public Comment Period, and Adjourn.

Public Comment Period: Just before the adjourning of each day the chair of the board will ask those in the room and in the virtual meeting if there are any oral public comments. If there are, the chair will call on each person to speak. The individual will have up to 5 minutes to address the board. After oral comments are given any written comments will be read by the Designated Federal Officer (DFO).

Meeting Accessibility: Pursuant to 5 U.S.C. 1009(a) and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public. The meeting will be held via videoconference. If you wish to attend by videoconference you must register at this link: *https://www.zoomgov.com/meeting/register/vJIsdeyhpjwpHl9VKp2r_gY9nUrFJsWzMxs.*

Once registered, the web address and audio number will be provided. For purposes of transparency and attendance reporting you will be required to use your actual first name and last name as your username.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Dr. Kimberly Spangler at 703–571–2477 (voice) no later than Friday, March 15, 2024 at 5:00 p.m. EST so that appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140 and 5 U.S.C. 1009(a)(3), interested persons may submit a written statement to the SERDP SAB. Individuals submitting a statement must submit their statement no later than 5:00 p.m. EST, Wednesday, March 20, 2024 to *kimberly.y.spangler.civ@mail.mil* (email) or to 703–571–2477 (voice). If a statement pertaining to a specific topic being discussed at the planned meeting is not received by Wednesday, March

20, 2024, prior to the meeting, then it may not be provided to, or considered by, the Committee during the March 21, 2024 meeting. The DFO, Dr. Kimberly Spangler will review all timely submissions with the SERDP SAB Chair and ensure such submissions are provided to the members of the SERDP SAB before the meeting.

Dated: February 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–05244 Filed 3–11–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0046]

Agency Information Collection Activities; Comment Request; Application for the U.S. Presidential Scholars Program

AGENCY: Office of Communication and Outreach (OCO), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before May 13, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2024–SCC–0046. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov*. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments.

Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 4C210, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Simone Olson, 202–987–0886.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for the U.S. Presidential Scholars Program.

OMB Control Number: 1860–0504.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 3,300.

Total Estimated Number of Annual Burden Hours: 52,800.

Abstract: The United States Presidential Scholars Program is a national recognition program to honor outstanding graduating high school seniors. Candidates are invited to apply based on academic achievements on the SAT or ACT assessments, through nomination from Chief State School Officers, other recognition program partner organizations, on artistic merits based on participation in a national talent program and achievement in career and technical education programs. This program was established by Presidential Executive Orders 11155, 12158 and 13697.

Dated: March 7, 2024.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–05176 Filed 3–11–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; National Professional Development

AGENCY: Office of English Language Acquisition, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2024 for the National Professional Development (NPD) program, Assistance Listing Number 84.365Z. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: March 12, 2024.

Deadline for Notice of Intent to Apply: April 11, 2024.

Deadline for Transmittal of Applications: May 13, 2024.

Deadline for Intergovernmental Review: July 10, 2024.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *www.federalregister.gov/documents/2022/12/07/2022–26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.* Please note that these Common Instructions supersede the version published on December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Francisco J. López, Jr., U.S. Department of Education, 400 Maryland Ave. SW, Washington, DC 20202. Telephone: (202) 558–4880. Email: *NPD2024@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: Under the NPD program, authorized by sections

3111(c)(1)(C) and 3131 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), the Department awards grants to public and private nonprofit institutions of higher education (IHEs) and public and private entities with relevant experience and capacity, in consortia with State educational agencies (SEAs) and/or local educational agencies (LEAs) to implement pre-service and in-service professional development activities intended to improve instruction for English learners (ELs) and assist education personnel working with ELs to meet high professional standards. Grants awarded under this program may be used for effective pre-service professional development programs that will increase the number and diversity of fully licensed or certified bilingual or multilingual teachers. The purpose of the grants to be awarded under this competition is to increase the number of bilingual and multilingual teachers supporting ELs.

Background:

''Raise the Bar (RTB): Lead the World'' is the Department's call to action to transform prekindergarten through postsecondary learning and unite around what truly works by promoting academic excellence, boldly improving learning conditions, and preparing our Nation's students for global competitiveness.[1] To achieve these goals, we must work to eliminate the educator shortage, increase services for EL students, and expand pathways to multilingualism for all students.

The NPD program, specifically the pre-service component of NPD, is uniquely positioned to support the Department's RTB goals by helping to ensure that ELs have access to well-prepared educators and by quickly growing the number of qualified bilingual and multilingual educators needed to expand the availability of bilingual programs. As supported by the Native American Language Act of 1990 (NALA 1990) as amended by the Durbin Feeling Languages Act and sections 3127 and 3124(3) of the ESEA, we welcome participation from applicants proposing projects that increase the number of teachers who are bilingual or multilingual in a Native American language and a second language to support the unique needs of Native American EL students and expand pathways to multilingualism for all Native American students.

As described in the absolute priority, this competition is designed to support pre-service projects that recruit bilingual or multilingual teacher candidates and that propose to implement at least one grow-your-own (GYO) strategy as part of their overall objective of increasing the number of fully licensed or certified bilingual and multilingual teachers. Drawing upon partnerships with community-based organizations, school districts, and IHEs, GYO programs recruit students from local areas through outreach, close collaboration with school counselors and teachers, and meaningful opportunities to learn about and engage in the teaching profession. Along with financial support, participating students are provided academic, social and other support to ensure completion of the program (*e.g.,* stipends, licensure preparation, mentoring, and peer groups).[2] These programs may be designed for high school students who want to become educators or adults such as paraprofessionals who are working in schools but need the credentials to teach.

For example, bilingual and multilingual students who have earned the Seal of Biliteracy have demonstrated competencies in English and one or more other languages and could be strong potential participants in a GYO project. Since the inception of the Seal of Biliteracy in California in 2011, the program has been replicated in 48 States and the District of Columbia, each of which has approved its own statewide Seal of Biliteracy. Through the NPD program, we encourage projects that incentivize high school graduates who have received the seal to pursue a career as a bilingual or multilingual teacher. These students could also be supported through dual enrollment, early college, and Career and Technical Education programs that provide students interested in teaching with opportunities to earn related credits and other experiential related opportunities. Additionally, bilingual and multilingual paraprofessionals, high-quality substitute teachers, and others in a community who are interested in becoming bilingual or multilingual teachers are a valuable resource and may have strong connections to the local community. Providing them with support through GYO strategies may result in a quicker pathway to certification or licensure given any postsecondary credits they may already have.

As part of the FY 2024 NPD competition, we also aim to diversify the teacher workforce. Students, particularly emerging bilingual and multilingual students, from low-income backgrounds are a critical part of addressing the need to provide culturally and linguistically relevant teaching in underserved schools and to give all students the opportunity to benefit from diverse educators. Consistent with the Secretary's overall priorities, applicants are encouraged to propose projects that recruit, prepare, and retain students from low-income backgrounds, including those who live in rural areas or who are first-generation candidates, as they transition to and enroll in postsecondary education, including by helping students complete the FAFSA and secure additional financial support such as service scholarships. This may also include designing a pre-service program that removes barriers to participation by helping candidates who are from low-income backgrounds with tuition, fees, books, supplies, childcare, and transportation to and from pre-service classes as a few examples.

As the EL population continues to grow, and as our global economy becomes more interconnected, it is critical that we give every student every educational opportunity, which begins with teachers who are well prepared and supported and have the language, skills, knowledge, and cultural competencies to serve EL students.

Priorities: This notice includes one absolute priority, one competitive preference priority, and one invitational priority. In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priority is from the notice of priorities, requirements, and definitions for this program published elsewhere in this issue of the **Federal Register** (2024 NFP). The competitive preference priority is from the Administrative Priorities for Discretionary Grants Programs (Administrative Priorities), published in the **Federal Register** on March 9, 2020 (85 FR 13640).

Absolute Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, the following priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

The priority is:

Increase the Number of Bilingual or Multilingual Teachers Through a Grow-Your-Own (GYO) Pre-Service Program that Recruits Teacher Candidates who are Bilingual or Multilingual.

Projects that propose to increase the number of fully licensed or certified bilingual or multilingual teachers working in language instruction educational programs or serving ELs, and improve their qualifications and

[1] *www.ed.gov/raisethebar/.*

[2] *ies.ed.gov/ncee/edlabs/regions/northwest/pdf/strategies-for-educators.pdf.*

skills, through evidence-based (as defined in 34 CFR 77.1(c)) pre-service programs. Applicants must describe their plan for recruiting, supporting, and retaining teacher candidates who are bilingual or multilingual. Applicants must include in their proposed plan for a pre-service program, one or more of the following GYO strategies that are designed to address shortages of bilingual or multilingual teachers and increase the diversity of qualified individuals entering the educator workforce:

(a) Implementing evidence-based GYO strategies for bilingual or multilingual individuals (*e.g.,* creating dual enrollment, early college, and Career and Technical Education programs in teaching for middle and high school students paired with offering seals of biliteracy or supporting bilingual or multilingual paraprofessionals actively working in P–12 schools in becoming teachers).

(b) Recruiting bilingual or multilingual individuals who may have a teaching credential, but who are not certified to teach bilingual or multilingual education, and supporting them in earning the additional certification.

(c) Implementing evidence-based teacher residencies in bilingual or multilingual education, including scaling these evidence-based pathways through a registered teacher apprenticeship program.

Competitive Preference Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2), we award up to an additional five points to an application that meets the competitive preference priority. An applicant must clearly identify in the project abstract and the project narrative section of its application that it is addressing the competitive preference priority for purposes of earning competitive preference priority points.

This priority is:

Applications From New Potential Grantees (0 or 5 points).

(a) Under this priority, an applicant must demonstrate that it does not, as of the deadline date for submission of applications, have an active grant, including through membership in a group application submitted in accordance with 34 CFR 75.127–75.129, under the program from which it seeks funds.

(b) For the purpose of this priority, a grant or contract is active until the end of the grant's or contract's project or funding period, including any extensions of those periods that extend the grantee's or contractor's authority to obligate funds.

Invitational Priority: For FY 2024, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Service to Students from First-Generation or Low-Income Backgrounds.

Projects to recruit, prepare, and retain students in the pre-service program who are first-generation postsecondary students (*i.e.,* whose parents' highest level of education is a high school diploma or less) or who are from low-income backgrounds.

Application Requirements: An applicant must provide the indicators it proposes to use to determine if a participant meets the definition of ''bilingual or multilingual.'' Applicants may provide this information in response to the selection criteria, or otherwise as applicable, in their applications. (2024 NFP)

Definitions: The following definitions of ''bilingual or multilingual'' and ''pre-service'' are from the 2024 NFP.

Bilingual or multilingual means able to listen, speak, read, and write in two or more languages with at least a high level of proficiency in each language, as determined based on indicators of proficiency established by the grantee. Note, bilingual or multilingual means a high level of proficiency in the domains that exist for the language, which may be fewer than four domains for some languages.

Pre-service means the period of preparation for a person who does not have a prior teaching certificate or license and who is enrolled in a State-approved teacher education program that leads to a full State-approved certificate or license.

Program Authority: 20 U.S.C. 6861.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2024 NFP. (e) The Administrative Priorities.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $8,400,000.

The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program. Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $600,000-$700,000.

Maximum Award: $700,000 per year.

Estimated Number of Awards: 12.

Note: The Department is not bound by any estimates in this notice.

Project Period: 60 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, or public or private entities with relevant experience and capacity, in consortia with LEAs or SEAs.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

d. *Limitation on Awards:* To maximize student population needs and geographic diversity, the number of awards per single entity will be limited to one per DUNS or UEI number.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.* Please note that these Common Instructions supersede the version published on December 27, 2021.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the NPD competition, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Consistent with the process followed in prior NPD competitions, we may post the project narrative section of funded NPD applications on the Department's website so you may wish to request confidentiality of business information. Identifying proprietary information in the submitted application will help facilitate this public disclosure process.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application.We recommend that you (1) limit the application narrative to no more than 35 pages and (2) use the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit for the application does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the bibliography, or the letters of support of the application. However, the recommended page limit does apply to the entire narrative section of the application. An application will not be disqualified if it exceeds the recommended page limit.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from section 34 CFR 75.210. The maximum score for all of these criteria is 100 points (not including competitive preference priority points). The maximum score for each criterion is indicated in parentheses.

(a) *Quality of the project design.* (up to 33 points)

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replication of project activities or strategies, including information about the effectiveness of the approach or strategies employed by the project.

(iii) The extent to which the proposed project demonstrates a rationale (as defined in 34 CFR 77.1(c)).

(b) *Quality of project personnel.* (up to 12 points)

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(c) *Quality of the management plan.* (up to 28 points)

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(d) *Adequacy of resources.* (up to 6 points)

(1) The Secretary considers the adequacy of resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(ii) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits.

(e) *Quality of the project evaluation.* (up to 21 points)

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iii) The extent to which the methods of evaluation will provide valid and reliable performance data on relevant outcomes.

2. *Review and Selection Process:* The Department will screen applications that are submitted for NPD grants in accordance with the requirements in this notice and determine which applications meet the eligibility and other requirements. Peer reviewers will review all eligible applications for NPD grants that are submitted by the established deadline.

Applicants should note, however, that we may screen for eligibility at multiple points during the competition process, including before and after peer review; applicants that are determined to be ineligible will not receive a grant award regardless of peer reviewer scores or comments. If we determine that an application does not meet an NPD requirement, the application will not be considered for funding.

For NPD grant applications, the Department intends to conduct a thorough and impartial review process to review and score all eligible applications. Content reviewers will review and score all eligible applications on the following selection criteria: (a) Quality of the project design; (b) Quality of project personnel; (c) Quality of the management plan; and (d) Adequacy of resources. Peer reviewers with evaluation expertise will review and score selection criterion (e) Quality of the project evaluation.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also. If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable

consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms.html.*

(c) The Secretary may provide a grantee with additional funding for data collection, analysis, and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* (a) The Department has established the following performance measures for the purpose of Department reporting under 34 CFR 75.110:

Measure 1: The percentage of project-specific annual goals the program met.

Measure 2: The number of bilingual or multilingual pre-service program participants enrolled annually.

Measure 3: Under measure 2, the number of bilingual or multilingual participants who are making progress toward becoming fully State certified, licensed, or endorsed in EL instruction.

Measure 4: Under measure 2, the number of bilingual or multilingual participants who have become fully State certified, licensed, or endorsed annually.

(b) *Indicators of success.* These measures constitute the Department's indicators of success for this program. Consequently, we advise an applicant for a grant under this program to carefully consider these measures in conceptualizing the approach for its proposed project plan.

(c) *Baseline data.* Applicants must provide baseline (as defined in 34 CFR 77.1) data in their applications for each of the project performance measures listed in (a) and explain how each proposed baseline is related to program outcomes; or, if the applicant has determined that there are no established baseline data for a particular performance measure, explain why there is no established baseline and explain how and when, during the project period, the applicant will establish a baseline for the performance measure.

(d) *Performance measure targets.* In addition, the applicant must propose in its application annual targets for the measures listed in paragraph (a). Applications must also include the following information as directed under 34 CFR 75.110(b):

(1) An explanation of how each proposed performance target is ambitious (as defined in 34 CFR 77.1) yet achievable compared to the baseline for the performance measure.

(2) An explanation of the data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and

(3) An explanation of the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

Note: If the applicant does not have experience with collection and reporting of performance data through other projects or research, the applicant should provide other evidence of capacity to successfully carry out data collection and reporting for its proposed project. The reviewers of each application will score related selection criteria based on how well an applicant has considered these measures in conceptualizing the approach and evaluation of the project.

(e) *Performance Reports.* All grantees must submit an annual performance report and final performance report with information that is responsive to these performance measures. The Department will consider this data in making annual continuation awards.

(f) *Department Evaluations.* Consistent with 34 CFR 75.591, grantees funded under this program must comply with the requirements of any evaluation of the program conducted by the Department or an evaluator selected by the Department.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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

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

your search to documents published by the Department.

Montserrat Garibay,

Assistant Deputy Secretary and Director for the Office of English Language Acquisition.

[FR Doc. 2024–05206 Filed 3–8–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a virtual meeting of the Basic Energy Sciences Advisory Committee (BESAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, April 9, 2024; 10:00 a.m. to 5:30 p.m. EDT.

Wednesday, April 10, 2024; 10:00 a.m. to 3:00 p.m. EDT.

ADDRESSES: This meeting is open to the public. This meeting will be held virtually via Zoom. Information to participate can be found on the website closer to the meeting date at *https://science.osti.gov/bes/besac/Meetings.*

FOR FURTHER INFORMATION CONTACT: Kerry Hochberger; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (301) 903–7661 or email: *kerry.hochberger@science.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of this Committee is to make recommendations to DOE–SC concerning the basic energy sciences research program.

Tentative Agenda

Tuesday, April 9, 2024

- Call to Order, Introductions, Review of the Agenda
- Updates on 2023 BESAC Charges
- Update from the Office of Science
- Update from the Office of Basic Energy Sciences
- Panel Discussion: Scientific Progress in Biomolecular Materials
- Additional Discussions of 2023 BESAC Charges
- Public Comment
- Adjourn

Wednesday, April 10, 2024

- 2023 BESAC Facilities Charge Report-Out/Discussion
- Public Comment
- Adjourn

Breaks taken as appropriate.

Public Participation: The meeting is open to the public. A webcast of this meeting will be available. Please check the website below for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Kerry Hochberger at *kerry.hochberger@science.doe.gov.* You must request an oral statement at least five business days before the meeting. Reasonable provisions will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. If you have any questions or need a reasonable accommodation under the Americans with Disabilities Act for this event, please send your request to Kerry Hochberger at *kerry.hochberger@science.doe.gov* two weeks but no later than 48 hours, prior to the event. Closed captions will be enabled. Information about the committee can be found at: *https://science.osti.gov/bes/besac.*

Minutes: The minutes of this meeting will be available for review on the U.S. Department of Energy's Office of Basic Energy Sciences website at: *https://science.osti.gov/bes/besac/Meetings.*

Signing Authority: This document of the Department of Energy was signed on March 7, 2024, by David Borak, Deputy Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 7, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–05243 Filed 3–11–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–68–000]

National Fuel Gas Supply Corporation; Notice of Application and Establishing Intervention Deadline

Take notice that on February 23, 2024, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed an application under section 7(b) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations, requesting authorization to abandon by sale to Lenape Resources LLC its Derby Storage Field, including all facilities associated with the field, located in the Town of Evans, and three other wells (the New Oregon Road Wells) located in the Town of North Collins, Erie County, New York, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*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. Public access to records formerly available in the Commission's physical Public Reference Room, which was located at the Commission's headquarters, 888 First Street NE, Washington, DC 20426, are now available via the Commission's website. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY (202) 502–8659.

Any questions regarding the proposed project should be directed to Alice A. Curtiss, Deputy General Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221, by phone at (716) 857–7075, or by email at *curtissa@natfuel.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for

[1] 18 CFR (Code of Federal Regulations) 157.9.

Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on March 27, 2024. How to file protests, motions to intervene, and comments is explained below.

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*.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before March 27, 2024.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–68–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24–68–000).

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[7] and the regulations under the NGA[8] by the intervention deadline for the project, which is March 27, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp*.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24–68–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf*.; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

intervene must reference the Project docket number CP24–68–000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Protests and motions to intervene must be served on the applicant either by mail or email at: Alice A. Curtiss, Deputy General Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221 or at *curtissa@natfuel.com*. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp*.

Intervention Deadline: 5:00 p.m. Eastern Time on March 27, 2024.

Dated: March 6, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–05229 Filed 3–11–24; 8:45 am]

BILLING CODE 6717–01–P

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

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: EC24–53–000.

Applicants: Dunns Bridge Energy Storage, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Dunns Bridge Energy Storage, LLC, et al.

Filed Date: 3/5/24.

Accession Number: 20240305–5250.

Comment Date: 5 p.m. ET 3/26/24.

Docket Numbers: EC24–56–000.

Applicants: Burgess Biopower, LLC, North Country Generation Holdings LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Burgess BioPower, LLC, et al.

Filed Date: 3/5/24.

Accession Number: 20240305–5253.

Comment Date: 5 p.m. ET 3/26/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–2708–010.

Applicants: PJM Interconnection, L.L.C., Potomac-Appalachian Highline Transmission, LLC.

Description: Refund Report: Potomac-Appalachian Highline Transmission, LLC submits tariff filing per 35.19a(b): Potomac-Appalachian submits Refund Report in Docket No. ER12–2708 to be effective N/A.

Filed Date: 3/6/24.

Accession Number: 20240306–5069.

Comment Date: 5 p.m. ET 3/27/24.

Docket Numbers: ER21–2722–001.

Applicants: E. BarreCo Corp LLC.

Description: Refund Report: Refund report to be effective N/A.

Filed Date: 3/6/24.

Accession Number: 20240306–5105.

Comment Date: 5 p.m. ET 3/27/24.

Docket Numbers: ER24–227–002.

Applicants: RPC Power, LLC.

Description: Tariff Amendment: Response to Deficiency Letter-Indicative Screens (ER24–227–) to be effective 1/20/2024.

Filed Date: 3/6/24.

Accession Number: 20240306–5134.

Comment Date: 5 p.m. ET 3/27/24.

Docket Numbers: ER24–1412–000.

Applicants: OhmConnect, Inc.

Description: 205(d) Rate Filing: Normal filing 2024 to be effective 3/6/2024.

Filed Date: 3/5/24.

Accession Number: 20240305–5214.

Comment Date: 5 p.m. ET 3/26/24.

Docket Numbers: ER24–1415–000.

Applicants: AEP Texas Inc.

Description: 205(d) Rate Filing: AEPTX–Louise Solar 1st A&R Generation Interconnection Agreement Cancellation to be effective 3/16/2024.

Filed Date: 3/6/24.

Accession Number: 20240306–5052.

Comment Date: 5 p.m. ET 3/27/24.

Docket Numbers: ER24–1416–000.

Applicants: AEP Texas Inc.

Description: 205(d) Rate Filing: AEPTX–Buckeye Corpus Christi Generation Interconnection Agreement Cancellation to be effective 4/8/2024.

Filed Date: 3/6/24.

Accession Number: 20240306–5057.

Comment Date: 5 p.m. ET 3/27/24.

Docket Numbers: ER24–1417–000.

Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii: AEP submits one Facilities Agreement re: ILDSA, No. 1262 to be effective 6/1/2024.

Filed Date: 3/6/24.

Accession Number: 20240306–5078.

Comment Date: 5 p.m. ET 3/27/24.

Docket Numbers: ER24–1420–000.

Applicants: Sierra Estrella Energy Storage LLC.

Description: Baseline eTariff Filing: Application for MBR Authorization and Request for Waivers to be effective 3/18/2024.

Filed Date: 3/6/24.

Accession Number: 20240306–5155.

Comment Date: 5 p.m. ET 3/27/24.

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.

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: March 6, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–05231 Filed 3–11–24; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0170, OMB 3060–0668, OMB 3060–0688; FR ID 207300]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before May 13, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0170.

Title: Section 73.1030, Notifications Concerning Interference to Radio Astronomy, Research and Receiving Installations.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents and Responses: 57 respondents; 57 responses.

Estimated Hours per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Cost: $14,250.

Total Annual Burden: 29 hours.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Needs and Uses: The information collection requirements contained in 47 CFR 73.1030 state in order to minimize harmful interference at the National Radio Astronomy Observatory site located at Green, Pocahontas County, West Virginia, and at the Naval Radio Research Observatory at Sugar Grove, Pendleton County, West Virginia, a licensee proposing to operate a short-term broadcast auxiliary station pursuant to § 74.24, and any applicant for authority to construct a new broadcast station, or for authority to make changes in the frequency, power, antenna height, or antenna directivity of an existing station within the area bounded by 39°15′ N on the north, 78°30′ W on the east, 37°30′ N on the south, and 80°30′ W on the west, shall notify the Interference Office, National Radio Astronomy Observatory, P.O. Box 2, Green Bank, West Virginia 24944. Telephone: (304) 456–2011. The notification shall be in writing and set forth the particulars of the proposed station, including the geographical coordinates of the antenna, antenna height, antenna directivity if any, proposed frequency, type of emission and power. The notification shall be made prior to, or simultaneously with, the filing of the application with the Commission. After receipt of such applications, the FCC will allow a period of 20 days for comments or objections in response to the notifications indicated. If an objection to the proposed operation is received during the 20-day period from the National Radio Astronomy Observatory for itself, or on behalf of the Naval Radio Research Observatory, the FCC will consider all aspects of the problem and take whatever action is deemed appropriate.

(2) Any applicant for a new permanent base or fixed station authorization to be located on the islands of Puerto Rico, Desecheo, Mona, Vieques, and Culebra, or for a modification of an existing authorization which would change the frequency, power, antenna height, directivity, or location of a station on these islands and would increase the likelihood of the authorized facility causing interference, shall notify the Interference Office, Arecibo Observatory, HC3 Box 53995, Arecibo, Puerto Rico 00612, in writing or electronically, of the technical parameters of the proposal. Applicants may wish to consult interference guidelines, which will be provided by Cornell University. Applicants who choose to transmit information electronically should email to: *prcz@naic.edu.*

(i) The notification to the Interference Office, Arecibo Observatory shall be made prior to, or simultaneously with,

the filing of the application with the Commission. The notification shall state the geographical coordinates of the antenna (NAD–83 datum), antenna height above ground, ground elevation at the antenna, antenna directivity and gain, proposed frequency and FCC Rule Part, type of emission, and effective radiated power.

(ii) After receipt of such applications, the Commission will allow the Arecibo Observatory a period of 20 days for comments or objections in response to the notification indicated. The applicant will be required to make reasonable efforts to resolve or mitigate any potential interference problem with the Arecibo Observatory and to file either an amendment to the application or a modification application, as appropriate. The Commission shall determine whether an applicant has satisfied its responsibility to make reasonable efforts to protect the Observatory from interference.

OMB Control Number: 3060–0668.

Title: Section 76.936, Written Decisions.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit entities; State or Local, or Tribal government.

Number of Respondents and Responses: 150 respondents; 150 responses.

Estimated Hours per Response: 1 hour.

Frequency of Response: Third party disclosure requirement; On occasion reporting requirement.

Total Annual Burden: 150 hours.

Total Annual Cost: No cost.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 4(i) of the Communications Act of 1934, as amended.

Needs and Uses: The information collection requirements contain in 47 CFR 76.936 require that a franchising authority must issue a written decision in a rate-making proceeding whenever it disapproves an initial rate for the basic service tier or associated equipment in whole or in part, disapproves a request for a rate increase in whole or in part, or approves a request for an increase whole or in part over the objection of interested parties. Franchising authorities are required to issue a written decision in rate-making proceedings pursuant to Section 76.936 so that cable operators and the public are made aware of the proceeding.

OMB Control Number: 3060–0688.

Title: Abbreviated Cost-of-Service Filing for Cable Network Upgrades, FCC Form 1235.

Form Number: FCC Form 1235.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities; State, local or tribal governments.

Number of Respondents and Responses: 10 respondents; 5 responses.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Estimated Hours per Response: 10–20 hours.

Total Annual Burden: 150 hours.

Total Annual Costs: No cost.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Needs and Uses: FCC Form 1235 is an abbreviated cost of service filing for significant network upgrades that allows cable operators to justify rate increases related to capital expenditures used to improve rate-regulated cable services. FCC Form 1235 is filed following the end of the month in which upgraded cable services become available and are providing benefits to subscribers. In addition, FCC Form 1235 can be filed for pre-approval any time prior to the upgrade services becoming available to subscribers using projected upgrade costs. If the pre-approval option is exercised, the operator must file the form again following the end of the month in which upgraded cable services become available and are providing benefits to customers of regulated services, using actual costs where applicable.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–05233 Filed 3–11–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1030; FR ID 207658]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before May 13, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1030.

Title: Service Rules for Advanced Wireless Services (AWS) in the 1.7 GHz and 2.1 GHz Bands.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; state, local, or tribal government; Federal Government and not for-profit institutions.

Number of Respondents: 357 Respondents; 2,835 responses.

Estimated Time per Response: 0.25 to 5 hours.

Frequency of Response: Annual, semi-annual, one time, and on occasion reporting requirements, recordkeeping

requirement, third-party disclosure requirements, and every ten years reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in sections 1, 2, 4(i), 201, 301, 302, 303, 307, 308, 309, 310, 316, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, and sections 6003, 6004, and 6401 of the Middle Class Tax Relief Act of 2012, Public Law 112–96, 126 Stat. 156, 47 U.S.C. 151, 152, 154(i), 201, 301, 302(a), 303, 307, 308, 309, 310, 316, 319, 324, 332, 333, 1403, 1404, and 1451.

Total Annual Burden: 8,118 hours.

Total Annual Cost: $576,000.

Needs and Uses: The currently approved information collections under Control No. 3060–1030 relate to three groups of Advanced Wireless Service (''AWS'') spectrum, commonly referred to as AWS–1, AWS–3, and AWS–4. The FCC's policies and rules apply to application, licensing, operating and technical rules for this spectrum. The respondents are AWS licensees, incumbent Fixed Microwave Service (FS) and Broadband Radio Service (BRS) licensees that relocate out of the AWS bands. AWS licensees also have coordination requirements with certain Federal Government incumbents.

Recordkeeping, reporting, and third-party disclosure requirements associated with the FCC items listed in item 1 of the supporting statement will be used by incumbent licensees and new entrants to negotiate relocation agreements and to coordinate operations to avoid interference. The information also will be used by licensees to determine reimbursement obligations of other licensees pursuant to the Commission's rules, and notify to notify such licensees of their reimbursement obligations. Additionally, the information will be used to facilitate dispute resolution and for FCC oversight of the cost-sharing plan.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–05234 Filed 3–11–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[MB Docket No. 11–43; DA 24–184; FRS ID 206900]

Audio Description: Nonbroadcast Networks

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: FCC announces the top five national nonbroadcast networks subject to the Commission's audio description requirements.

DATES: The updated list of the top five national nonbroadcast networks subject to the Commission's audio description requirements is effective July 1, 2024.

ADDRESSES: The full text of this public notice is available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat via ECFS and at *https://www.fcc.gov/document/media-bureau-grants-requests-audio-description-exemption-0.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

FOR FURTHER INFORMATION CONTACT: For further information, contact Diana Sokolow (202–418–0588; *Diana.Sokolow@fcc.gov*).

SUPPLEMENTARY INFORMATION: This is a summary of the Media Bureau's Public Notice, DA 24–184, released on February 28, 2024. Audio description makes video programming more accessible to individuals who are blind or visually impaired through ''[t]he insertion of audio narrated descriptions of a television program's key visual elements into natural pauses between the program's dialogue.'' [1] The Commission's audio description rules require multichannel video programming distributor (MVPD) systems that serve 50,000 or more subscribers to provide 87.5 hours of audio description per calendar quarter on channels carrying each of the top five national nonbroadcast networks. The top five national nonbroadcast networks are defined by an average of the national audience share during prime time of nonbroadcast networks that reach 50 percent or more of MVPD households and have at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under the audio description rules.

The rules provide that the list of top five nonbroadcast networks will update at three-year intervals to account for changes in ratings, and that the fourth triennial update will occur on July 1, 2024, based on the 2022 to 2023 ratings year. In anticipation of this update, the Media Bureau issued a Public Notice on November 30, 2023 announcing the top ten nonbroadcast networks for the 2022 to 2023 ratings year according to data provided by the Nielsen Company: Fox News, ESPN, MSNBC, HGTV, Hallmark, TLC, TNT, TBS, Discovery, and History. The Public Notice indicated that a program network could seek an exemption no later than 30 days after publication of the Public Notice, if it believed it should be excluded from the list of top five networks covered by the audio description rules because it does not air at least 50 hours of prime time programming per quarter that is not live or near-live or is otherwise exempt. Fox News, ESPN, and MSNBC filed timely requests for exemption from the list of top five nonbroadcast networks.

In an Order adopted concurrently with this Public Notice, the Bureau found that Fox News, ESPN, and MSNBC provide on average less than 50 hours per calendar quarter of prime time programming that is not live or near-live. The Bureau, therefore, exempted these three networks from the Commission's audio description requirements applicable to the top five national nonbroadcast networks. In making its determination, the Bureau reviewed data pertaining to the six most recent calendar quarters submitted by each network and sample programming schedules. The Bureau also considered additional information each individual network submitted to support or explain aspects of each request, when available.

Thus, as a result of the exemptions granted to Fox News, MSNBC, and ESPN and a review of Nielsen ratings for the 2022 to 2023 ratings year, the top five nonbroadcast networks that will be subject to the audio description requirements as of July 1, 2024 are: HGTV, Hallmark, TLC, TNT, and TBS. MVPD systems that serve 50,000 or more subscribers must provide 87.5 hours of audio description per calendar quarter on channels carrying each of these networks during the triennial period beginning on July 1, 2024.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2024–05186 Filed 3–11–24; 8:45 am]

BILLING CODE 6712–01–P

[1] 47 CFR 79.3(a)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request; OMB No. 3064–0015

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the request to renew the existing information collections described below (OMB Control No. 3064–0015). The notice of the proposed renewal for this information collection was previously published in the **Federal Register** on November 2, 2023, allowing for a 60-day comment period.

DATES: Comments must be submitted on or before April 11, 2024.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency website: https://www.fdic.gov/resources/regulations/federal-register-publications/.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7 a.m. and 5 p.m.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION, CONTACT: Jennifer Jones, Regulatory Counsel, 202–898–6768, *jennjones@fdic.gov,* MB–3078, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

1. *Title:* Interagency Bank Merger Application.

OMB Number: 3064–0015.

Form Number: 6220/01.

Affected Public: FDIC-insured depository institutions.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

Information collection description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response	Estimated annual burden
Interagency Bank Merger Act Application—Affiliated Transactions.	Reporting	Mandatory	103	On Occasion ..	19	1,957
Interagency Bank Merger Act Application—Nonaffiliated Transactions.	Reporting	Mandatory	117	On Occasion ..	31	3,627

Total Estimated Annual Burden: 5,584 hours.

General Description of Collection: Section 18(c) of the Federal Deposit Insurance Act (FDI Act) requires an insured depository institution (IDI) that wishes to merge or consolidate with any other IDI or, either directly or indirectly, acquire the assets of, or assume liability to pay any deposits made in, any other IDI, to apply for the prior written approval of the responsible agency (the FDIC; the Board of Governors of the Federal Reserve (FRB); or the Office of the Comptroller of the Currency (OCC)).[1] Section 18(c) further requires FDIC approval in connection with any merger transaction involving an IDI and a non-insured entity.

The Interagency Bank Merger Act Application Form (Application Form) is used by the FDIC, the FRB, and the OCC for applications under Section 18(c) of the FDI Act. The Application Form may be used for any merger transaction subject to Section 18(c). There is a different level of burden for each of the two types of merger transactions, nonaffiliated and affiliated. An affiliate transaction refers to a merger, consolidation, other combination, or transfer of any deposit liabilities, between an IDI and another entity controlled by the same parent company, regardless of whether the other entity is FDIC-insured. It includes a business combination between an IDI and an affiliated interim institution. Applicants proposing affiliate transactions are not required to complete questions 12 through 14 of the Application Form. If the merging entities are not controlled by the same parent company, the merger transaction is considered nonaffiliated, and the applicant must complete the entire application form.

The FDIC Supplement to the Interagency Bank Merger Act Application Form (Supplement) requires each applicant to provide information that delineates the relevant geographic market(s) and describes the competition in the relevant geographic market(s). The information collected focuses on the relevant geographic market(s) where the applicant and the entity to be acquired provide banking products or services. The Supplement includes specific instructions to facilitate a comprehensive competitive analysis relative to transactions between nonaffiliated entities.

There is no change in the method or substance of the collection. The 62-hour decrease in burden hours is the result of updated data available.

[1] 12 U.S.C. 1828(c). The FDIC is the responsible agency if the acquiring, assuming, or resulting bank is to be a State nonmember insured bank or a State savings association.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on March 6, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–05166 Filed 3–11–24; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements

under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201421.

Agreement Name: Agency Agreement.

Parties: Arkas Container Transport SA; Turkon Container Transportation & Shipping, Inc.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Agreement authorizes Turkon America Inc. to acts as the U.S. agent of Arkas Container Transport S.A. (''Arkas'') with respect to Arkas' services in the trades between the U.S. Atlantic Coast on the one hand and countries bordering the Black and Mediterranean Seas, Western Europe, Northern Europe, and West and North Africa. The parties have requested expedited review.

Proposed Effective Date: 04/15/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/86551.

Agreement No.: 012426–007.

Agreement Name: The OCEAN Alliance Agreement.

Parties: American President Lines, LLC; APL CO. PTE. LTD; CMA CGM S.A.; COSCO Shipping Lines Co., Ltd; Evergreen Line Joint Service Agreement; OOCL (Europe) Limited; Orient Overseas Container Line Limited.

Filing Party: Robert Magovern; Cozen O'Connor.

Synopsis: This Amendment revises Article 7 to extend the term of the Agreement through March 31, 2032.

Proposed Effective Date: 04/15/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1214.

Dated: March 6, 2024.

Alanna Beck,

Federal Register Alternate Liaison Officer.

[FR Doc. 2024–05144 Filed 3–11–24; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 11, 2024.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *FB Bancorp, Inc., New Orleans, Louisiana;* to become a bank holding company by acquiring Fidelity Bank, New Orleans, Louisiana, a state-chartered mutual savings bank (Bank), in connection with Bank's conversion from mutual to stock form.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–05236 Filed 3–11–24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to implement the Whistleblower Intake Guide (FR 30; OMB No. 7100–NEW).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Implementation of the Following Information Collection

Collection title: Whistleblower Intake Guide.

Collection identifier: FR 30.

OMB control number: 7100–NEW.

Dates: This information collection will be effective April 11, 2024.

General description of collection: The Whistleblower Intake Guide collects information regarding alleged misconduct or retaliation by a Board-

supervised institution or an affiliated party of such institution. The information collected through the FR 30 assists in the Board's supervision of financial institutions.

Frequency: Event-generated.

Respondents: Employees of Board-supervised entities and members of the public.

Total estimated number of respondents: 5.

Estimated average hours per response: 0.5.

Total estimated annual burden hours: 3.[1]

Current actions: On September 8, 2023, the Board published a notice in the **Federal Register** (88 FR 62084) requesting public comment for 60 days on the implementation of the FR 30. The comment period for this notice expired on November 7, 2023. The Board did not receive any comments. The FR 30 will be implemented as originally proposed.

Board of Governors of the Federal Reserve System, March 6, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–05139 Filed 3–11–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0077]

Early Alzheimer's Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Early Alzheimer's Disease: Developing Drugs for Treatment.'' This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of the stages of sporadic Alzheimer's disease (AD) that occur before the onset of overt dementia. This draft guidance revises the previous draft guidance for industry of the same name issued on February 16, 2018.

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 30.

DATES: Submit either electronic or written comments on the draft guidance by May 13, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–0077 for ''Early Alzheimer's Disease: Developing Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Teresa Buracchio, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4212, Silver Spring, MD 20993–0002, 240–402–4274; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Early Alzheimer's Disease: Developing Drugs for Treatment.'' This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of the stages of sporadic AD that occur before the onset of overt dementia. This draft guidance revises the draft guidance for industry entitled ''Early Alzheimer's Disease: Developing Drugs for Treatment'' issued February 16, 2018 (83 FR 7060), and reflects FDA's consideration of public comments on the draft guidance. This revision describes FDA's current thinking regarding the use of biomarkers for the selection of participants with early stages of AD for enrollment in clinical trials, the selection of outcome measures for clinical trials in early AD, and the use of effects on characteristic pathophysiological changes of AD to support approval in these populations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Early Alzheimer's Disease: Developing Drugs for Treatment.'' 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 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: March 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05178 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0869]

Advisory Committee; Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmaceutical Science and Clinical Pharmacology Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the January 22, 2026, expiration date.

DATES: Authority for the Pharmaceutical Science and Clinical Pharmacology Advisory Committee will expire on January 22, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993, 301–796–9001, *ACPS-CP@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics that such drugs purport or are represented to have, and as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner. The Committee may also review Agency-sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

Pursuant to its charter, the Committee shall consist of a core of 14 voting members including 2 Chairpersons. Members and Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, and microbiology) and clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations, and innovative methods in drug development), biostatistics, related biomedical and pharmacological specialties, current good manufacturing practices, and quality systems implementation. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee will serve either as Special Government Employees or non-voting representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who

is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to three non-voting representative members who are identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/pharmaceutical-science-and-clinical-pharmacology-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05218 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–5847 and FDA–2019–E–5855]

Determination of Regulatory Review Period for Purposes of Patent Extension; Light Adjustable Lens

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LIGHT ADJUSTABLE LENS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by May 13, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 9, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2019–E–5847 and FDA–2019–E–5855 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; LIGHT ADJUSTABLE LENS.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device LIGHT ADJUSTABLE LENS. LIGHT ADJUSTABLE LENS is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag in adult patients: with pre-existing corneal astigmatism of greater than or equal to 0.75 diopters and without pre-existing macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors. Subsequent to this approval, the USPTO received patent term restoration applications for LIGHT ADJUSTABLE LENS (U.S. Patent Nos. 6,851,804 and 6,905,641) from RxSight, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 21, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of LIGHT ADJUSTABLE LENS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LIGHT ADJUSTABLE LENS is 3,346 days. Of this time, 3,031 days occurred during the testing phase of the regulatory review period, while 315 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* September 26, 2008. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on February 1, 2008. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on September 26, 2008, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* January 12, 2017. The applicant claims December 9, 2016, as the date the premarket approval application (PMA) Light Adjustable Lens (PMA P160055) was initially submitted. However, FDA records indicate that PMA P160055 was initially submitted on January 12, 2017, when a complete application was submitted.

3. *The date the application was approved:* November 22, 2017. FDA has verified the applicant's claim that PMA P160055 was approved on November 22, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,825 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05213 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0758]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's procedures for early food safety evaluation and consultations for new plant varieties intended for food use, including biotechnology-derived food plants.

DATES: Either electronic or written comments on the collection of information must be submitted by May 13, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–0758 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; New Plant Varieties Intended for Food Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance

of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Plant Varieties Intended for Food Use

OMB Control Number 0910–0583—Extension

This information collection supports recommendations found in FDA guidance pertaining to new plant varieties intended for food use.

I. Consultation Procedures: Foods Derived From New Plant Varieties; Form FDA 3665

The Agency guidance document entitled ''Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived From New Plant Varieties'' (October 1997), which is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant,* describes our consultation process for the evaluation of information on new plant varieties provided by developers. We believe this consultation process will help ensure that human and animal food safety issues or other regulatory issues (*e.g.,* labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development and will help to ensure that market entry decisions by the industry are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Since 1992, when we issued our ''Statement of Policy: Foods Derived From New Plant Varieties'' (the 1992 policy) (57 FR 22984, May 29, 1992), we have encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with us during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, we explained that under the FD&C Act developers of new foods (in this document food refers to both human and animal food) have a responsibility to ensure that the foods they offer to consumers are safe and in compliance with all requirements of the FD&C Act. To initiate a New Plant Variety consultation (also known as a Biotechnology Notification File (BNF)), developers are encouraged to electronically submit their scientific information and data following a step-by-step process to complete Form FDA 3665, assemble their notification, and send fully electronic submissions to FDA via the Center for Food Safety and Applied Nutrition Online Submission Module (COSM), which may be accessed at *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm.* Firms that prefer to submit a paper notification in a paper format of their choosing or as electronic files on physical media with a paper signature page, have the option to do so; however, Form FDA 3665 prompts a notifier to input the elements of a BNF in a standard format that we will be able to review efficiently. Form FDA 3665 may be accessed at *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

II. Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Form FDA 3666

Since we issued the 1992 policy on foods derived from new plant varieties, including those varieties that are developed through biotechnology, we have encouraged developers of new plant varieties to consult with us early in the development process to discuss possible scientific and regulatory issues that might arise. The guidance, entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' (June 2006), which is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced,* continues to foster early communication by encouraging developers to submit to us their evaluation of the food safety of their new proteins. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of the new protein.

We believe that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins produced by new plant varieties, including biotechnology-derived food plants, and the procedures for communicating with us about the safety evaluation. To initiate an Early Food Safety Evaluation consultation (also known as a New Protein Consultation (NPC)), developers are encouraged to electronically submit their scientific information and data following a step-by-step process to complete Form FDA 3666, assemble their notification, and send fully electronic submissions to FDA via COSM, which may be accessed at *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm.* Firms that prefer to submit a paper NPC in a paper format of their choosing or as electronic files on physical media with a paper signature page, have the option to do so; however, Form FDA 3666 prompts a notifier to input the elements of an NPC in a standard format that we will be able to review efficiently. Form FDA 3666 may be accessed at *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Agency guidance recommendations; information collection	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Consultation Procedures: Foods Derived From New Plant Varieties						
Initial consultation	None	30	2	60	4	240
Final consultation	3,665	12	1	12	150	1,800
Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use						
Six data components	3,666	6	1	6	20	120
Total	.....	.....	.....	78	.....	2,160

[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 minor adjustments to update our burden estimate to reflect recent annual response rates (increased initial consultations under the New Plant Variety consultation procedures) and to clarify the total number of responses under the Early Food Safety Evaluation (NPC) procedures.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05219 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0783]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements in the Agency's regulations relating to establishment registration and product listing for manufacturers of human blood and blood products and licensed devices.

DATES: Either electronic or written comments on the collection of information must be submitted by May 13, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–0783 for ''Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices—21 CFR Part 607

OMB Control Number 0910–0052—Extension

This information collection helps support implementation of section 510 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360), as well as related Agency regulations in 21 CFR part 607 and forms. All owners or operators of establishments that manufacture human blood and blood products are required to register with the FDA, unless they are exempt under 21 CFR 607.65. A list of every blood product manufactured, prepared, or processed for commercial distribution must also be submitted, among other information. Establishments must register within 5 days after beginning operations or submission of a biologics license application, and register annually between October 1 and December 31.

The regulations set forth procedures and requirements pertaining to establishment registration and product listing for manufactures of human blood and blood products and licensed devices, including initial registration and product listing, annual registration, product listing updates and waiver requests. Owners or operators of certain establishments that engage in the manufacture of blood products must register and submit a list of every blood product in commercial distribution (21 CFR 607.20(a)). Initial and subsequent registrations and product listings must be submitted electronically through FDA's Center for Biologics Evaluation and Research (CBER) Blood Establishment Registration and Product Listing system through the FDA Industry Systems page available at *https://www.access.fda.gov.* More information about the eBER system is available at: *https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing.* Online instructions are available at: *https://www.fda.gov/media/116432/download?attachment.* The Form FDA 2830 previously associated with this information collection is no longer in use.

FDA may grant a request for waiver of this requirement prior to the date on which the information is due (21 CFR 607.22(a)). Waiver requests must be submitted in writing and must include, among other information, the specific reasons why electronic registration is not reasonable for the registrant.

Establishment registration and product listing information assists FDA in its inspections of facilities, among other uses, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply.

Description of Respondents: Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, independent laboratories that engage in quality control and testing for registered blood product establishments and manufacturers of devices licensed under section 351 of the Public Health Service Act.

We estimate the burden of the information collection 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
607.20(a), 607.21, 607.22, 607.25, 607.40; Initial registration and submission of product listing.	176	1	176	1	176
607.21, 607.22, 607.25, 607.26, 607.31, 607.40; Annual registration.	2,545	1	2,545	0.5 (30 minutes)	1,273
607.21, 607.25, 607.30(a), 607.31, 607.40; Product listing update.	42	1	42	0.25 (15 minutes)	10

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
607.22(b); Written waiver request	1	1	1	1	1
Total					1,460

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

Based on our evaluation of calendar year 2022 data from CBER's Blood Establishment Registration and Product Listing system, we have adjusted the currently approved burden estimate we attribute to establishment registration and product listing to reflect a decrease in product listing updates and an increase in the number of initial registrations. Our estimated burden for the information collection reflects an overall decrease of 36 hours.

Dated: March 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05215 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3847]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 April 11, 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 0910–0308. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Adverse Experience Reporting for Licensed Biological Products; and General Records—21 CFR Part 600

OMB Control Number 0910–0308—Extension

This information collection helps support implementation of statutory and regulatory authorities that govern adverse experience reporting. Under the Public Health Service Act (PHS Act) (42 U.S.C. 262), FDA may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to ensure its safe use. Regulations implementing adverse experience reporting (AER) requirements applicable to biological products are codified in part 600 (21 CFR part 600). Regulations applicable to combination products subject to regulations in part 600 are found in part 4 (21 CFR part 4)—Regulation of Combination Products. The collections of information are intended to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to biologics licensed under any provision of section 351 of the PHS Act.

To assist respondents with the reporting provisions of the information collection, FDA has created both paper-based and electronic forms. Information may be submitted electronically through *MEDWATCH* or the *Vaccine Adverse Experience Reporting System* (VAERS). AER reports are filed using the MEDWATCH Form FDA–3500A (approved under OMB control numbers 0910–0291 and 0910–0645) or the VAERS–1. Both versions of the forms and instructions are available from the internet at *https://vaers.hhs.gov.* The forms may also be downloaded, completed, and submitted to the Agency by mail or facsimile.

For operational efficiency, on March 20, 2023, we requested, and OMB has approved, the addition of burden attributable to provisions set forth in part 4, subpart B, previously included in OMB control number 0910–0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of the combination product is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103. Relatedly, § 4.104 explains how and where to submit reports.

In the **Federal Register** of September 28, 2023 (88 FR 66856), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment regarding our estimate of 28 hours per response for periodic adverse experience reports. The comment suggested we lower that estimate but provided no data or explanation in support of the proposed reduction. While we have therefore made no adjustment in our burden estimate, we encourage further comment regarding a basis for assessing burden for the scope of information collection activity covered by the applicable regulations and associated forms.

Respondents: Respondents to this collection of information are manufacturers of biological products (including blood and blood

components) and any person whose name appears on the label of a licensed biological product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—BIOLOGICAL PRODUCTS [1]

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
600.80(c)(1), 600.80(d), and 600.80(e); postmarketing 15-day Alert Reports	109	3,806.95	414,958	1	414,958
600.82; notification of discontinuance or interruption in manufacturing	23	1.435	33	2	66
600.80(c)(2); Periodic Adverse Experience Reports	109	3,697	402,973	28	11,283,244
600.81; distribution reports	172	5.727	985	1	985
600.80(h)(2), 600.81(b)(2), and 600.90; waiver requests	35	1.886	66	1	66
Total					11,699,319

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—BIOLOGICAL PRODUCTS [1]

21 CFR Section; activity	Number of recordkeepers	Numbers of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours
600.12 [2]; Maintenance of Records	131	40.145	5,259	32	168,288
600.12(b)(2); Recall Records	216	3.4028	735	24	17,640
600.80(c)(1) and 600.80(k); AER Records	109	7,503.95	817,931	1	817,931
Total					1,003,859

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN—COMBINATION PRODUCTS [1]

21 CFR Section; activity	Number of respondents	Number of disclosures per respondents	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
4.102, 4.103, 4.104, 4.105; Postmarketing Safety Reporting for Combination Products, including associated reports and sharing information with other constituent part applicants.	11	18	198	0.35 (21 minutes)	69

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

The burden for this information collection has changed since the last OMB approval. The reporting and recordkeeping burden has increased mostly due to an increase in the number of AER reports submitted to FDA and the associated recordkeeping with these reports. We have also added burden we believe attributable to post marketing safety reporting and attendant recordkeeping and disclosures, as required under part 4, subpart B.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05222 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice of a meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will convene the 80th full council meeting on Wednesday, March 27–Thursday, March 28, 2024. The meeting will be open to the public and there will be a public comment session during the meeting; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, March 18, 2024. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Thursday, April 4, 2024. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will convene on Wednesday, March 27, 2024 from approximately 10:00 a.m. (Eastern) –7:00 p.m. (Eastern) and Thursday, March 28, 2024 from approximately 10:00 a.m. (Eastern) to 4:45 p.m. (Eastern).

ADDRESSES: Texas Southern University, 3100 Cleburne Avenue, Houston, TX 77004. To attend the meeting virtually, please visit *www.hhs.gov/live.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Senior Management Analyst, at *PACHA@hhs.gov* or *Caroline.Talev@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended

by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 14109, dated September 29, 2023. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. The functions of the Council are solely advisory in nature.

The Council consists of not more than 35 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, population health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. PACHA selections also include persons with lived HIV experience and persons disproportionately affected by HIV. Council members are appointed by the Secretary.

Dated: February 21, 2024.

Caroline Talev,

Senior Management Analyst, Office of Infectious Disease and HIV/AIDS Policy, Alternate Designated Federal Officer, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2024–05183 Filed 3–11–24; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990-new]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 13, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: OASH Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements.

Type of Collection: New.

OMB No. 0990–NEW–Office of the Assistant Secretary for Health.

Abstract: The Office of the Assistant Secretary for Health (OASH) is seeking OMB approval on a new information collection, the OASH Standard Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements (hereafter the OASH PPR). The purpose of this data collection is to gather quantitative and qualitative information common to the assessment of recipient performance on individual grants and cooperative agreements (collectively, grants) managed in OASH. OASH will collect common data elements measuring the performance of each recipient against the approved grant project plan, including progress toward goals and outcomes as required by 45 CFR 75.342(b)(2).

OASH oversees a broad range of grant programs within the Office of the Secretary (OS), Department of Health and Human Services (HHS). The current active OASH programs with discretionary grants (with assistance listing number) include: Public Awareness Campaigns on Embryo Adoption (93.007); Research on Research Integrity (93.085); Advancing System Improvements for Key Issues in Women's Health (93.088); Community Programs to Improve Minority Health Grant Programs (93.137); Family Planning Services (93.217); Family Planning Personnel Training (93.260); Teenage Pregnancy Prevention Program (93.297); Public Health Service Evaluation Funds (93.343); Research, Monitoring and Outcomes Definitions for Vaccine Safety (93.344); Minority HIV/AIDS Fund (93.899); Family Planning Service Delivery Improvement Research Grants (93.974); and National Health Promotion (93.990). OASH grants span a wide range of project types, including service, demonstration project, evaluation, research, training, and conference projects. Within each program, the awards are subdivided into cohorts aligned with the notices of funding opportunity under which OASH competed the awards. Currently, there are 47 cohorts of active awards across OASH. In any given year, OASH programs collectively monitor 450–550 active awards with another 200–300 inactive awards awaiting final reports as a prerequisite to closing the grant.

The collection is needed to enhance project performance information and simplify reporting under 45 CFR 75.301. Each recipient currently must submit a quarterly Federal Financial Report (FFR or SF–425) (45 CFR 75.341) and a periodic Performance Progress Report (PPR) for each grant (45 CFR 75.342(b)(2). PPR reporting periods in OASH are scheduled quarterly, semi-annually, or annually, depending on the need determined by the program office using a narrative format that can vary by cohort. The PPR schedule is specifically aligned with the quarterly FFRs whenever possible to create a complete snapshot of the project's progress at the end of the reporting period.

The common elements identified in the new collection for OASH programs will standardize the collection of the required information (45 CFR 75.342(b)(2)) including: (1) a comparison of the actual accomplishments to the objectives of the award for the period; (2) the reasons why established goals were not met; and (3) pertinent information, analysis and explanation of cost overruns or high unit costs. The common elements include reporting on publications, including data sets and other work products, to facilitate implementation of OSTP Memorandum Ensuring Free, Immediate, and Equitable Access Federally Funded Research (August 25, 2022). The new information collection will limit the content of the report to those activities taking place during the reporting period (*i.e.,* quarterly, semiannually, or annually). The information collection is structured to facilitate program review across reporting periods. This will allow OASH to identify and improve program outcomes, share lessons learned, and spread the adoption of promising practices among its grant recipients and other HHS awarding agencies.

The content of the new collection is structured for web-based data collection under 7 headings: Report Header; Project Progress; Significant Project

Accomplishments; Broader Program Impacts; Products and Dissemination; Collaboration and Partnering Activities; and Project Evaluation Activities. Information will be prepopulated based on the login credentials for the user submitting the report and the specific grant being reported. Not all grants will have reportable activities under all headings (*e.g.,* not all grants have an evaluation component embedded in the project). However, most OASH grants will have reportable information under most headings. Program offices with additional reporting programmatic information collections will eventually transition collection of any overlapping data elements to this OASH PPR. During the transition, OASH will not require grant recipients to provide the same information twice.

Likely Respondents: Members and staff from academia, community organizations, local/state/federal government, private sector, and tribal government and services organizations.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
OASH PPR	OASH grant recipients	800	3	1	2400
Total					2400

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–05162 Filed 3–11–24; 8:45 am]

BILLING CODE 4150–48–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK X01 Central Repository Non-renewable Sample Access review meeting.

Date: April 4, 2024.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Peter J. Kozel, Ph.D., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7009, Bethesda, MD 20892, (301) 594–4721, *kozelp@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 6, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–05161 Filed 3–11–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowship Review Meeting.

Date: April 5, 2024.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John F. Connaughton, Ph.D., Chief, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, *connaughtonj@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 6, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–05160 Filed 3–11–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 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: Integrative Vascular Biology and Hematology Hypertension.

Date: April 3, 2024.

Time: 9:00 a.m. to 5:30 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: Dmitri V. Gnatenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *gnatenkod2@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Atherosclerosis and Vascular Biology.

Date: April 5, 2024.

Time: 1:00 p.m. to 8:30 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*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Adaptive and Innate Immunity Special Emphasis Panel.

Date: April 5, 2024.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, *susan.boyle-vavra@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: March 6, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–05179 Filed 3–11–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7090–N–04]

60-Day Notice of Proposed Information Collection: Moving to Work Stepped and Tiered Rent Demonstration Evaluation, OMB Control No.: 2528–0339

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* May 13, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Moving to Work (MTW) Cohort 2 Stepped and Tiered Rent Demonstration Evaluation.

OMB Approval Number: 2528–0339.

Type of Request: Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: HUD has selected 10 Public Housing Agencies (PHAs) to participate in the second cohort of the Moving to Work (MTW) Expansion, Stepped and Tiered Rent Demonstration (STRD). These PHAs will implement an alternative rent policy (a stepped rent or tiered rent) that is intended to reduce PHA administrative burden and increase self-sufficiency of assisted households. Five PHAs will implement a stepped rent and five PHAs will implement a tiered rent. HUD's Office of Policy Development and Research (PD&R) will evaluate the impacts of those alternative rent policies, using a randomized controlled trial. The evaluation will rely on data from a variety of sources, including new information collection efforts proposed in this Notice. HUD has contracted with MDRC to conduct the first phase of the evaluation, including random assignment, baseline data collection, and monitoring PHA implementation.

Within the 10 participating PHAs, eligible households will be randomly assigned to have their rent calculated under the new rules (stepped/tiered rent) or old rules (the Brooke rent, typically 30% of household income). Eligible households will be non-elderly, non-disabled participants in the public housing and housing choice voucher program. Prior to random assignment, each household will be asked to complete a baseline information form (BIF), review the informed consent form, and provide informed consent to authorize HUD's evaluator to use their data for the evaluation. The BIF will provide important information not otherwise available from HUD's administrative data, such as whether the household has significant barriers to employment. The BIF will average approximately 7 minutes long and reviewing the consent form is expected to take approximately 11 minutes.

MDRC will also conduct interviews with staff from participating PHAs, to better understand their experience implementing the new rent policies. For

the first phase of the evaluation, MDRC is expected to conduct two rounds of staff interviews with each PHA. During the first round, MDRC expects to interview up to ten staff per PHA (reflecting a mix of executive management staff, public housing and HCV directors, and public housing and HCV specialists). The second round will focus on staff most directly involved with implementing the new rent policies (public housing and HCV directors and/or managers, and public housing and HCV specialists). The mode in Round 1will be a mix of one-on-one interviews and group interviews, with small groups of 2–3 staff performing similar roles. The mode in Round 2 will be group interviews, with groups of 2–4 staff performing similar roles.

MDRC will collect data extracts that will include a small subset of data elements captured by the PHAs exclusively for the demonstration, called the ''Rent Policy Implementation Data Tracking Tool.'' MDRC will collect these data fields along with MTW Expansion 50058 data, which is collected under OMB control number 2577–0083, directly from PHAs during the early implementation period to ensure that the new rent rules are being implemented correctly and throughout the demonstration to track hardship requests and collect updated contact information for ongoing communications and reminders about the demonstration and for potential follow-up surveys.

Respondents (*i.e.,* affected public): Recipients of HUD housing assistance participating in the Stepped and Tiered Rent Demonstration; Staff with PHAs participating in the Demonstration.

Estimated Number of Respondents: up to 25,000 study participants who will complete the baseline survey; 100 PHA staff interviewees in a first round (which occurred in 2023) and up to 120 PHA staff interviewees in a second round of data collection with staff.

Frequency of Response: Once (BIF); Once for staff included in Round 1 staff interviews; Once for staff included in Round 2 staff interviews.

Average Hours per Response: The BIF will take 7 minutes per response (.12 hour). PHA staff interviews will take one hour, on average, in Round 1. Round 2 staff interviews will take up to 90 minutes.

Total Estimated Burdens:

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Baseline Information Form (household survey)	24,000	1	24,000	.12	2,880	$9.43	$27,158.40
Stepped Rent Informed Consent Form	7,000	1	7,000	.18	1,260	9.43	11,881.80
Tiered Rent Informed Consent Form	17,000	1	17,000	.18	3,060	9.43	28,855.80
PHA Executive Director Interviews (Round 1)	10	1	10	.75	7.5	59.86	448.95
PHA Program Director Interviews (Round 1)	20	1	20	1.5	30	44.24	1,327.20
PHA MTW Coordinator Interviews (Round 1)	10	1	10	.75	7.5	44.24	331.80
PHA Housing Specialist Interviews (Round 1)	60	1	60	1.5	90	25.64	2,307.60
Rent Policy Implementation Data Tracking Tool	10	1	10	9	90	25.64	2,307.60
PHA Program Director/Manager Interviews (Round 2)	40	1	40	1.5	60	46.83	2,809.80
PHA Housing Specialist Interviews (Round 2)	80	1	80	1.5	120	27.00	3,240.00
Total	48,230				7,605		80,668.95

Households in the STRD will range widely in employment position and earnings. We have estimated the average prevailing minimum hourly wage across the ten STRD sites at $9.43.

For program staff participating in interviews in Round 1, the estimate uses the mean hourly wages of selected occupations (classified by Standard Occupational Classification (SOC) codes) was sourced from the Occupational Employment Statistics from the U.S. Department of Labor's Bureau of Labor Statistics. Potentially relevant occupations and their median hourly wages in the ''Local Government, excluding Schools and Hospitals'' industry are:

Occupation	SOC code	Mean hourly wage rate
Community and Social Service Specialist	21–1099	$25.64
Social and Community Service Manager	11–9151	44.24
Chief Executives	11–1011	59.86

Source: Occupational Employment Statistics, accessed online December 20, 2021 at *http://www.bls.gov/oes/current/oes_stru.htm.*

For program staff participating in interviews in Round 2, the estimate uses the mean hourly wages of selected occupations (classified by Standard Occupational Classification (SOC) codes) was sourced from the Occupational Employment Statistics from the U.S. Department of Labor's Bureau of Labor Statistics. Potentially relevant occupations and their median hourly wages are:

Occupation	SOC code	Mean hourly wage rate
Community and Social Service Specialist (Local Government)	21–1099	$27.00
Social/community Service Manager (Local Government)	11–9151	46.83

Source: 2022 Occupational Employment Statistics, accessed online December 21, 2023 at *http://www.bls.gov/oes/current/oes_stru.htm.*

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy, Development and Research.

[FR Doc. 2024–05175 Filed 3–11–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7090–N–02]

60-Day Notice of Proposed Information Collection: License for the Use of Personally Identifiable Information Protected Under the Privacy Act of 1974, OMB Control No.: 2528–0297

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* May 13, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: License for the Use of Personally Identifiable Information Protected Under the Privacy Act of 1974.

OMB Approval Number: 2528–0297.

Type of Request: Reinstatement without change of a previously approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The United States Department of Housing and Urban Development (HUD) collects and maintains personally identifiable information on tenants in public and assisted housing, the confidentiality of which is protected by the Privacy Act of 1974 (5 U.S.C. 552a). On occasion, HUD shares this information with contractors and grantees, subject to stringent requirements to protect these households from unauthorized disclosure of information. The purpose for sharing is to further policy-relevant research on the effectiveness of HUD programs.

HUD may, under the terms of its Routine Use Inventory (77 FR 17361), share these data with parties whom HUD has awarded contracts, grants, or service agreements. HUD has shared data with contractors and grantees, but it has not until now shared data under service agreements because it has not until now proposed a legal form for effectuating such an agreement. HUD does not wish to limit access to the information to parties that have received specific funding to carry out a study through a grant or contract. Instead, HUD proposes to share the data with legitimate research organizations that have conceived policy-relevant analyses and that are able and willing to protect the data from unauthorized disclosure. The legal form for the proposed service agreement is herein called a ''license.''

HUD wishes to continue making the data available for statistical, research, or evaluation purposes to organizations and qualified and capable of research and analysis consistent with the statistical, research, or evaluation purposes for which the data were provided or are maintained, but only if the data are used and protected in accordance with the terms and condition stated in the license, upon receipt of such assurance of qualification and capability, and it is agreed by the organization requesting such information and HUD.

Members of affected public: Individuals in a research compacity of an organization or academic institution.

Estimated Number of Respondents: 15.

Estimated Time per Response: 1 hour.

Frequency of Response: Once annually.

Estimated Total Annual Burden Hours: 82.75 hours.

Estimated Total Annual Cost: The total estimated cost is $4,215.94.

Respondent's Obligation: Voluntary.

Legal Authority: This application form is conducted under Title 12, U.S.C., section 1701z–1 *et seq.*

Respondents: Organizations.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Annual cost
Appendix A: Data License Application	15	1	15	1	15	$47.31	$709.65
Appendix B: Data License Agreement	15	1	15	1	15	57.63	864.45
Appendix C: Affidavit of Nondisclosure	45	1	45	0.25	11.25	23.41	263.36
Annual Report	40	1	40	1	40	57.63	2,305.20
Appendix D: Data File Destruction Form	6	1	6	0.25	1.5	48.85	73.28
Total Burden Hours					82.75		4,215.94

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy, Development and Research.

[FR Doc. 2024–05157 Filed 3–11–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–NWRS–2024–N008; FXRS126109HD000–245–FF09R23000; OMB Control Number 1018–New]

Agency Information Collection Activities; Submission to the Office of Management and Budget; Programmatic Clearance for U.S. Fish and Wildlife Service Social Science Research

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before April 11, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice at *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. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference ''1018–USFWS Programmatic'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Madonna Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act 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.

On October 2, 2023, we published in the **Federal Register** (88 FR 67792) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on December 1, 2023. In an effort to increase public awareness of, and participation in, our public commenting processes associated with information collection requests (ICRs), the Service also published the **Federal Register** notice on *Regulations.gov* (Docket No. FWS–HQ–NWRS–2023–0126). We received five comments (described below) in response to that notice:

Comments 1 and 2: Two comments objected to collecting information from specific populations and the effectiveness of survey's information collection tools.

Agency Response to Comments 1 and 2: Input from a variety of populations and recreation groups is critical to a robust understanding of potential impacts from management, planning, and policy decisions. Information collection and understanding social landscapes help the Service better meet its mission of working with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American People. The agency took no action to unilaterally exclude public input from certain recreation groups or prevent stakeholder input as a tool to inform decisions.

Comment 3: One comment was about the appropriate use of animals for hunting, fishing, and trapping.

Agency Response to Comment 3: The agency took no action from this comment, as it is unrelated to the information collection.

Comments 4 and 5: Two comments were supportive the use of information collection to better understand customers. One of these comments also discussed methods to improve inclusivity and reduce agency burden with the use of technology.

Agency Response to Comments 4 and 5: The agency appreciates support of its efforts and suggestions to improve information collection. When appropriate, individual information collections may include methods such

as online data collection or QR code recruitment. As noted in comment 5, it may be more difficult to reach certain populations, and reaching these populations may necessitate the use of sampling methods such as in-person recruitment. The agency took no action, as each information collection submitted through this clearance will be evaluated if sampling methods appropriately reach the population of interest.

On April 17, 2020, we published in the **Federal Register** (85 FR 21450) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on June 16, 2020. We did not receive any comments in response to that notice.

On October 12, 2016, we published in the **Federal Register** (81 FR 70437) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on December 12, 2016. We received three nonsubstantive comments in response to that notice which did not address the information collection comments. No responses were required to those comments.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Monitoring and evaluating U.S. Fish and Wildlife Service (Service) activities, including the activities of the National Wildlife Refuge System (Refuge System), is an essential component of strategic and adaptive management. The collection of information is necessary to enable the Service to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improved service delivery and customer experience. In particular, collection of information and rigorous social science inquiries are necessary for the Service to fulfil the goals of the President's Executive Order (E.O.) 14008, Tackling the Climate Crisis at Home and Abroad; the principles of the Service's community-focused Urban Wildlife Conservation Program; a commitment to serving a broader and more diverse public; and a better understanding of the needs and perspectives of Tribal Nations and Native communities.

The proposed programmatic clearance would cover social science surveys, interviews, and focus groups designed to provide information to Service managers and practitioners to improve quality and utility of agency programs, services, and planning efforts. To ensure continuous improvement, Service activities and projects require ongoing systematic assessment of their design, implementation, and outcomes. Data from collections undertaken through the proposed programmatic clearance would provide information for planning, monitoring, and evaluating Refuge System efforts, as well as efforts of other Service programs. The scope of this programmatic clearance includes individual surveys; focus groups; and interviews of refuge visitors, potential visitors, residents of communities near Service-managed units, and stakeholders and partners, including Tribal interests.

The President's E.O. 14008 sets the goal of conserving ''at least 30 percent of our lands and waters by 2030,'' through the Conserving and Restoring America the Beautiful campaign. A collaborative approach is needed to achieve the principles for locally led efforts and better understand the patterns and trends occurring across public lands and waters. The Service's national visitor survey is one approach to collecting information from the public related to visitation across the Refuge System. The national visitor survey seeks to understand the recreation trends and experiences of visitors at refuges to better manage for future visitation that aligns with national conservation goals. One of the recommendations for early focus and progress in the America the Beautiful campaign is the increase of access to outdoor recreation, a management objective that the monitoring data from the visitor survey can help to inform.

The Service's Urban Wildlife Conservation program (Urban program) was established as a means to engage with urban communities more meaningfully in fish and wildlife conservation. It enumerates designation criteria for urban wildlife refuges (urban refuges), partnerships, and bird treaty cities, and describes how the standards of excellence apply to urban refuges and other urban activities. The Urban program aligns particularly well with the Department of the Interior's focus on equity and environmental justice, work that helps to achieve one of the President's Four Pillars (Racial Equity). Another recommendation outlined in the Conserving and Restoring America the Beautiful campaign includes creating safe outdoor opportunities in nature-deprived communities, a goal of which the Urban program is helping to achieve.

The Service is required to ''evaluate and adapt'' the practices of the Urban program through internal review of the urban entities by the Division of Visitor Services and Communications every 5 years, including an expanded visitor services review for the Urban Refuges as per Policy 110 FW 1. The Division ''must analyze the people they are reaching and conduct approved visitor use surveys to monitor the changes and track audience engagement.'' In addition, the Service is committed to evaluating progress and measuring success of the Urban Program's standards of excellence, such as ''know and relate to the community; connect urban residents with nature through the steppingstones of engagement; and ensure visitors feel safe and welcome.''

The Service's Human Dimensions (HD) Branch, programmatically aligned within the National Wildlife Refuge System, will serve as the office of control for the programmatic clearance.

The role of the HD Branch is to build conservation social science understanding, capacity, and integration within the Service. A suite of questions will serve as the basis for all information collections under this programmatic clearance. The suite of questions will be used to develop surveys to respond to the above-named Presidential Priorities as well as adaptively ensure improved customer experience and satisfaction. As the office of control, the HD branch ICR Coordinator will conduct the necessary quality control, including assuring that each survey instrument comports with the guidelines of the programmatic clearance.

We developed the following topic areas within the suite of questions to streamline the ICR process:

(1) *Respondent Characteristics* (*e.g.,* demographics, land and property characteristics, and visits to other public lands). This topic area allows us to understand customer demographic profiles and track visitation trends more holistically over time.

(2) *Communication* (*e.g.,* languages spoken, sources of information used, and use of social media and other web-based outlets). This topic area allows us to understand customer preferences for finding information.

(3) *Trip Planning and Logistics* (*e.g.,* purpose of trip, information on wayfinding used, and various trip characteristics). This topic area allows us to understand the logistics and information involved with a customer's trip planning experience and make strategic transportation decisions.

(4) *Recreation Activities, Experiences, and Preferences* (*e.g.,* recreation activity preferences, experience, and satisfaction). This topic area allows us to better why customers visit, understand preferences for wildlife-dependent recreation, and provide a quality customer experiences at specific sites.

(5) *Knowledge, Attitudes, and Beliefs* (*e.g.,* understanding and opinions around nature, the outdoors, climate change, and the agency). This topic area allows us to improve future programming and communications with customers.

(6) *Resource Management Perceptions and Preferences* (*e.g.,* attitudes around resource protection, transportation needs, and other management decisions). This topic area allows us to understand current customer perceptions and anticipate how customers would most likely react to future management actions.

(7) *Visitor Expenditures and Economic Inputs* (*e.g.,* trip expenses, information on local businesses, and landowner contributions). This topic area allows us to gather economic data related to conservation goals of the agency.

(8) *Public, Stakeholder, and Partner Engagement* (*e.g.,* participation in programs, partnerships, and various conservation actions). This topic area allows us to understand if and how the customer dedicates their time to conservation-related actions.

(9) *Program Evaluation* (*e.g.,* learning outcomes, program experience rating, and satisfaction). This topic area allows us to better assess overall program outcomes and performance to improve future programming.

To qualify for the generic programmatic review process, each individual collection under this programmatic clearance must be well defined in terms of its sample or respondent pool and research methodology, it should clearly fit within the overall plan and scope of the approved ICR, and the survey questions must show a clear tie to Service management needs. Individual collections may not raise any controversial policy issues, include topics of significant public interest, or go beyond the methods specified and approved by OMB in this programmatic ICR. Any individual collection that requests nonagency goal-related data or information on controversial topics would be inappropriate for expedited review under this programmatic clearance and must go through the full PRA clearance process to solicit public feedback. In instances where HD Branch staff are involved with the development of the individual information collection, other uninvolved staff in the HD Branch or a member of the ICR review team would review the ICR.

We will obtain OMB approval of all individual survey submissions developed using the pre-approved suite of questions before the survey can be initiated. If, after consultation with the principal investigator, the ICR coordinator recommends a proposed survey for approval, both the Service and Departmental Information Collection Clearance Officers will review the ICR before it is formally transmitted to OMB for review and approval.

Title of Collection: Programmatic Clearance for U.S. Fish and Wildlife Service Social Science Research.

OMB Control Number: 1018–New.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Persons visiting units managed by the Service; potential visitors, including ''virtual visitors'' who access content from a Service website; local community members; educators taking part in programs both on and off Service lands; government officials representing the local area; landowners; partners; stakeholders; and Tribal interests.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Mode	Annual estimates		
	Number of respondents	Completion time per response (avg. minutes)	Burden hours **
On-site, mail, internet surveys *	20,333	20	6,778
Telephone surveys	833	25	347
All nonresponse surveys	784	5	65
Focus groups/in-person interviews	59	60	59
Annual Total	22,009	.....	7,249
3-Year Total	66,027	.....	21,747

* Includes 2-minute contact time for some surveys, interviews, and focus groups, and approximately 2,500 electronic surveys.
** All figures are rounded.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2024–05184 Filed 3–11–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–JAO–2024–0029; FXGO16621010070–245–FF10G13100; OMB Control Number 1018–New]

Agency Information Collection Activities; Improving Our Understanding of How Trout Anglers Differ in Their Valuations Between Wild and Hatchery Trout

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before May 13, 2024.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (please reference ''1018-Trout Angler Survey'' in the subject line of your comments):

- *Internet (preferred): https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–JAO–2024–0029.
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Fish and Wildlife Act of 1956 (16 U.S.C. 742(a)–754) establishes a comprehensive national fish and wildlife policy and authorizes the Secretary of the Interior to take steps required for the development, management, advancement, conservation, and protection of fisheries resources and wildlife resources through research, acquisition of refuge lands, development of existing facilities, and other means. The Service, working with others, is responsible for conserving, protecting, and enhancing fish and wildlife and their habitats for the continuing benefit of the American people through Federal programs relating to migratory birds, endangered species, interjurisdictional fish and marine mammals, and inland sport fisheries.

Pursuant to this mission, the Service acts as a trustee for injured natural resources when oil or hazardous substances are spilled or released into the environment. Through data collected, scientific assessment techniques, and extrapolated through economic analyses, trustees seek to identify the natural resources injured from oil or hazardous substances, determine the extent of the injuries, recover damages from those responsible, and plan and carry out restoration activities. The primary benefit of the Service's Natural Resource Damage Assessment and Response (NRDAR) program is to achieve restoration of injured resources for the benefit of the American people, and at no cost. This program seeks compensation from responsible parties to restore natural resources for all and allows all Americans to enjoy clean and safe public rivers and lands.

One aspect of the NRDAR program relates to releases of oil or hazardous substances that result in the loss of wild trout populations. When wild trout populations are killed or injured during a release event, one remedy includes using hatchery trout to replace wild trout populations. The potential problem with this approach is that there is substantial anecdotal evidence that trout anglers view and value catching wild trout and hatchery trout differently. If anglers value wild trout lost in a spill or release more highly than hatchery trout, then they may not have been made fully whole by a restoration action that substitutes hatchery trout for wild trout.[1] An examination of existing trout angler valuation studies found that, in the

[1] Department of the Interior regulations at 43 CFR 11.83 state that trustees may recover the replacement and/or acquisition of equivalent natural resources capable of providing such services (as injured) along with the compensable value of the services lost to the public through the completion of the baseline restoration, rehabilitation, replacement, and/or acquisition of equivalent natural resources.

majority of cases, no attempt was made to distinguish between angler values associated with fishing for hatchery vs. wild trout. This collection proposes a random survey of licensed anglers designed to elicit data sufficient to estimate any differences in preferences and values associated with fishing for wild vs. hatchery trout. The data generated through the proposed information collection will provide theoretically sound and statistically defensible estimates of angler experience values for use in gauging required compensation levels for lost or injured trout resources. For the current collection, State-licensed angler populations from three States are included, focusing on three distinct trout fishing regions of the United States.

Legal and administrative justifications for this collection can be found under 43 CFR part 11, Natural Resource Damage Assessments, through the authority of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended, (CERCLA; 42 U.S.C. 9601 *et seq.*), and the Clean Water Act (CWA; 33 U.S.C. 1251–1376), which gives Federal agencies authority to assess damages to natural resources resulting from a release of a hazardous substance or a discharge of oil covered under CERCLA or the CWA and to seek recovery for those damages.

The proposed collection and subsequent analysis will be used by the Service and other NRDAR trustees to improve methods used to properly compensate trout anglers for fishery injuries. The surveys will be designed to support the estimation of the appropriate ''compensation ratio'' between lost wild trout and hatchery trout used in restoration activities. This information will be used specifically by economists and other analysts tasked with assessing damages and scaling restoration activities.

Further, while the primary goal of the collection is limited to estimating the appropriate compensation ratio between wild and hatchery trout, valuation data will also be collected to allow further refinement of this ratio by area of the Nation, type of water fished, type of fishing gear used, and consumptive vs. catch-and-release fishing, to allow results to be applied in future NRDAR cases across different geographies and demographics.

This study includes a repeat contact mail-back/electronic survey of a random sample of licensed anglers drawn from three representative U.S. States (yet to be determined). We plan to contact a total of 3,000 licensed anglers (1,000/State). Based on previous survey efforts using similar methods, we expect an average response rate of 40 percent across the 3 States, yielding 1,200 completed responses. The total burden for this one-time collection is estimated to be 300 hours.

Mail/Online Follow-up Visitor Survey: The current collection benefits from and builds on a successful Minnesota (MN) 2021 survey instrument [2] which incorporated a very similar structure, length, and willingness to pay elicitation question format. This MN random household mail survey was anticipated to have a 14-to-16 percent response rate—typical for this type of unsolicited random household survey. The final response rate for the MN survey was 21 percent, which was considered very good given the methodology and protocol used. This response rate also reflects the interest the general public has in the subject matter. For the Service's mail-back/internet surveys, the population (licensed anglers being asked about fishing) is much more targeted and engaged than the population for general random household surveys. The potential respondents are already engaged in the activity being surveyed, and, based on previous National Park Service (NPS) research that the project team has been involved in, are predisposed to cooperate with the survey effort. For this reason and based on the NPS visitor Socioeconomic Monitoring Program (SEM) mail-back response rates, it is anticipated that response rates for the Service's mail-back/online survey will be 40 percent. Assuming a 40 percent response rate (n=1,200; 400/State) with a completion time of 15 minutes, the mail-back/online survey will result in a total burden of 300 hours.

Title of Collection: Improving Our Understanding of How Trout Anglers Differ in Their Valuations Between Wild and Hatchery Trout.

OMB Control Number: 1018–New.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Individuals/households (licensed anglers drawn from three representative U.S. States).

Total Estimated Number of Annual Respondents: 1,200 (400 respondents from 3 States).

Total Estimated Number of Annual Responses: 1,200.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 300.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2024–05185 Filed 3–11–24; 8:45 am]

BILLING CODE 4333–15–P

[2] The Minnesota survey and associated report were prepared for: Western Transportation Institute, College of Engineering, Montana State University and Nevada Department of Transportation NAS–NRC, for the following larger project: Wildlife Vehicle Collision (WVC) Reduction and Habitat Connectivity Task 1—Cost Effective Solutions Transportation Pooled-Fund Project TPF–5(358) (Administered by: Nevada Department of Transportation).

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2024–N005; FXMB1231099BPP0–245–FF09M32000; OMB Control Number 1018–0171]

Agency Information Collection Activities; Submission to the Office of Management and Budget; Establishment of Annual Migratory Bird Hunting Seasons

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to revise a currently approved information collection.

DATES: Interested persons are invited to submit comments on or before April 11, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice at *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. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and

Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference ''1018–0171'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request (ICR), contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 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.

On November 20, 2023, we published in the **Federal Register** (88 FR 80745) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on January 19, 2024. In an effort to increase public awareness of, and participation in, our public commenting processes associated with information collection requests, the Service also published the **Federal Register** notice on *Regulations.gov* (Docket No. FWS–HQ–MB–2023–0211), to provide the public with an additional method to submit comments (in addition to the typical U.S. mail submission methods). We received two comments in response to that notice which did not address the information collection requirements. No response to those comments is required.

In addition to soliciting public comments on the information collection requirements in the **Federal Register** notice, we consult annually with State and Tribal governments annually and on an ongoing basis throughout the rulemaking process. The Service publishes a series of proposed and final rulemaking documents for the establishment of the upcoming annual hunting seasons. Follow-up **Federal Register** publications discuss and propose the frameworks for the upcoming season migratory bird hunting regulations. Comments and recommendations are summarized and published as part of a follow-on proposed rule.

In addition, we also conduct consultation and outreach as part of this process through the involvement of the flyway councils. Acknowledging regional differences in hunting conditions, the Service has administratively divided the Nation into four flyways for the primary purpose of managing migratory game birds. Each flyway (Atlantic, Mississippi, Central, and Pacific) has a flyway council, a formal organization generally composed of one member from each State and Province in that flyway. The flyway councils, established through the Association of Fish and Wildlife Agencies, also assist in researching and providing migratory game bird management information for Federal, State, and provincial governments, as well as private conservation entities and the general public.

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 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: Migratory game birds are those bird species so designated in conventions between the United States and several foreign nations for the protection and management of these birds. Under the Migratory Bird Treaty Act (16 U.S.C. 703–712), the Secretary of the Interior is authorized to determine when ''hunting, taking, capture, killing, possession, sale, purchase, shipment, transportation, carriage, or export of any such bird, or any part, nest, or egg'' of migratory game birds can take place, and to adopt regulations for this purpose. These regulations are written after giving due regard to ''the zones of temperature and to the distribution, abundance, economic value, breeding habits, and times and lines of migratory flight of such birds'' (16 U.S.C. 704(a)) and are updated annually. This responsibility has been delegated to the Service as the lead Federal agency for managing and conserving migratory birds in the United States. However, migratory bird management is a cooperative effort of State, Tribal, and Federal governments. Migratory game bird hunting seasons provide opportunities for recreation and sustenance; aid Federal, State, and Tribal governments in the management of migratory game birds; and permit harvests at levels compatible with migratory game bird population status and habitat conditions.

The Service develops migratory game bird hunting regulations by establishing the frameworks, or outside limits, for season dates, season lengths, shooting hours, bag and possession limits, and areas where migratory game bird hunting may occur. Acknowledging regional differences in hunting conditions, the Service has administratively divided the Nation into four flyways for the primary purpose of managing migratory game birds. Each flyway (Atlantic, Mississippi, Central, and Pacific) has a flyway council, a formal organization generally composed of one member from each State and in that flyway. The flyway councils, established through the Association of Fish and Wildlife Agencies, also assist in researching and providing migratory game bird management information for Federal, State, provincial, and Tribal governments, as well as private conservation entities and the general public.

The information identified below, solicited annually from State (including

U.S. territory) governments, is necessary to establish annual migratory bird hunting seasons. The required information, received at various times in the year prior to the actual hunting season as part of the rulemaking process described above, is used by the Service as part of the final rulemaking process necessary to open annual hunting seasons otherwise closed by law.

1. *Information Requested from States and U.S. Territories to Establish Annual Migratory Bird Hunting Seasons*—State and U.S. territory governments that wish to establish annual migratory game bird hunting seasons are required to provide the requested dates and other details for hunting seasons in their respective States or Territories. The information is provided to the Service in a non-form format, usually via letter or spreadsheet, in response to solicitations for the information sent to the State governments each year via an emailed letter and as part of the first final rule (for the frameworks).

2. *Reports (50 CFR part 20)*—The following reports are requested from the States and are submitted either annually or every 3 years as explained in the following text. (Note: Below, we have annotated changes, if any, to the reporting requirements since OMB's last approval.)

a. Reports from Experimental Hunting Seasons and Season Structure Changes (Required):

i. *Atlantic Flyway Council:*

• Delaware—Experimental tundra swan season (yearly updates and final report). (*Removed—completed.*)

• Connecticut, Maryland, North Carolina, and Virginia—Evaluation of the two zone and three segment duck season zone-split configuration, including impacts on hunter dynamics (*e.g.,* hunter numbers, satisfaction) and harvest during the 2021–25 seasons (final report for each State). (*New.*)

ii. *Mississippi Flyway Council:*

• Alabama—Experimental sandhill crane season (yearly updates and final report). (*Removed—completed.*)

• Minnesota—Experimental early teal season (yearly updates and final report).

• Louisiana—Evaluation of the two zone and three segment duck season zone-split configuration, including impacts on hunter dynamics (*e.g.,* hunter numbers, satisfaction) and harvest during the 2021–25 seasons (final report). (*New.*)

iii. *Central Flyway Council:*

• New Mexico—Sandhill crane season in Estancia Valley (yearly updates and final report). Now operational—Annual data are still required, but there is not a final report, since this monitoring will occur in perpetuity (or as long as the State has that hunt area). (*Removed—experiment completed; moved to State-specific, below.*)

• South Dakota and Nebraska—Experimental two-tier hunting regulations study per the terms of the study plan and memorandum of agreement among these States and the Service (yearly updates and final report).

• Wyoming—Split (three-way) season for Canada geese (final report only). (*Removed—completed.*)

iv. *Pacific Flyway Council:*

• California—Split (three-way) season for white-fronted geese (final report only). (*Removed—completed.*)

• Idaho—Experimental swan season (yearly updates and final report). (*Removed—completed.*)

v. Additional State-Specific Annual Reports:

• Arizona—Sandhill crane season harvest and subspecies composition (3-year intervals).

• New Mexico—Sandhill crane season harvest and subspecies composition in Estancia Valley (yearly). (*Revised—relocated from Central Flyway Council experimental reports above.*)

• Delaware, North Carolina, and Virginia—Tundra swan season hunter participation and harvest (yearly). (*Revised to add Delaware.*)

• Montana (Central Flyway portion), North Dakota, and South Dakota—Tundra swan season hunter participation and harvest (yearly). (*Revised—relocated Montana and South Dakota to separate bullet, below.*)

• Montana (Central Flyway portion) and South Dakota—Swan season hunter participation, harvest, species composition, and hunter compliance rates in providing species-determinant parts or bill measurements of harvested swans for species identification (yearly). (*Revised.*)

• Idaho, Montana (Pacific Flyway Portion), Utah, and Nevada—Swan season hunter participation, harvest, species composition, and hunter compliance rates in providing species-determinant parts or bill measurements of harvested swans for species identification (yearly). (*Revised to add Idaho and Montana.*)

Reports and monitoring are used for a variety of reasons. Some are used to monitor species composition of the harvest for those areas where species intermingling can confound harvest management, and potential overharvest of one species can be of management concern. Others are used to determine overall harvest for those species and/or areas that are not sampled well by our overall harvest surveys due to either the limited nature/area of the hunt or season, or where the harvest requires close monitoring. Experimental season reports are used to determine whether the experimental season is achieving its intended goals and objectives, without causing unintended harm to other species and ultimately whether the experimental season should proceed to operational status. Most experimental seasons are 3-year trials with yearly reports and a final report. Most of the other reports and monitoring are conducted either annually or at 3-year intervals.

Proposed Revisions

1. *(REVISION) Submissions of Tribal Proposals*—Under the regulations in the Service's September 1, 2023, final rule (RIN 1018–BF64; 88 FR 60375), we removed the requirement that Tribes annually submit their proposed migratory game bird hunting regulations (and associated monitoring, anticipated harvest, and capabilities for regulation development and enforcement) for our review and approval. We also will no longer publish special Tribal migratory game bird hunting regulations in the **Federal Register** (*i.e.,* a proposed and final rule). The regulations set forth in the September 1, 2023, final rule adopted elements of our guidelines in use since 1985 for establishing special migratory game bird hunting regulations on Federal Indian reservations (including off-reservation trust lands) and ceded lands. Tribes that comply with these regulations will be authorized to independently establish special Tribal migratory bird hunting regulations. However, if circumstances change and data indicates migratory game bird populations are substantially declining or Tribal hunting increases significantly, we will reevaluate the regulations at 50 CFR 20.110.

By allowing Tribes to independently establish special migratory bird hunting regulations, the Service recognizes Tribal sovereignty to exercise reserved hunting rights and, for some Tribes, recognizes Tribal authority to regulate hunting by both Tribal and non-Tribal members on their reservations. The September 1, 2023, final rule extended to Tribes with reserved hunting rights the same autonomy as the States to independently establish migratory game bird hunting seasons for non-Tribal members within annually established, biologically appropriate Federal outside limits. As an alternative to promulgating special Tribal migratory game bird hunting regulations, Tribes may choose to observe the hunting regulations established by the State or States in

which the reservations are located. We coordinated with Tribes over the past 2 years via letters and four webinars as we developed this new regulatory approach for Tribal self- management of the harvest, and we have received positive feedback. The new system will reduce the annual administrative burden on both the Tribes and the Service to propose, review, and publish special migratory game bird hunting regulations while continuing to sustain healthy migratory game bird populations for future generations.

2. *(NEW) Requests for Consultation (Tribes/States)*—The new regulations in the final rule (88 FR 60375, September 1, 2023) also may be applied to the establishment of migratory game bird hunting regulations for non-Tribal members on all lands within the reservations where Tribes have full wildlife-management authority over such hunting, or where the Tribes and affected States otherwise have reached agreements over hunting by non-Tribal members on non-Indian lands within the reservation. Tribes usually have the authority to regulate migratory game bird hunting by nonmembers on Indian-owned reservation lands.

The question of jurisdiction is more complex on reservations that include lands owned by non-Indians, especially when the surrounding States have established or intend to establish regulations governing migratory game bird hunting by non-Indians on these lands. In those cases, we encourage the Tribes and States to reach agreement on regulations that would apply throughout the reservations. When appropriate, we will consult with a Tribe and State with the aim of facilitating an accord. We also will consult jointly with Tribal and State officials in the affected States where Tribes may wish to establish special migratory game bird hunting regulations for Tribal members on ceded lands.

It is incumbent upon the Tribe and/or the State to request consultation. We will not presume to make a determination, without being advised by either a Tribe or a State, that any issue is or is not worthy of formal consultation. Tribal and State requests for consultation with the Service should be sent to the Service's Assistant Director for the Migratory Bird Program. We note that our guidance on resolving issues of concern between Tribes and States on reservations and ceded lands is the same guidance we provided under the previous Tribal regulation process.

3. *(NEW) Requests for Experimental Seasons (Tribes)*—We will continue to consult with Tribes that wish to reach a mutual agreement (memorandum of understanding (MOU) or similar type of formal agreement) on conducting short-term (possibly several years) experimental hunting seasons using methods outside of the Federal hunting methods at 50 CFR 20.21 for on-reservation and ceded lands hunting by Tribal members. The Tribal-member-only experimental hunting season would provide data and evaluation criteria specified in an agreement for consideration if a Tribe would like to make the additional hunting method operational. Tribes should send such requests for consultation to the Service's Assistant Director for the Migratory Bird Program at least 9 months before the season or ceremony regarding hunting methods outside of the Federal regulations.

If any individual Tribe wishes to make these additional experimental hunting methods operational and the Service agrees, the Service will conduct rulemaking (using any data from the experimental hunting season) to amend 50 CFR part 20 to allow Tribal members to use these additional hunting methods.

Starting with the 2023–24 hunting season, annual Tribal hunting season regulations will no longer be published in the **Federal Register**, alleviating the administrative burden to both the Service and the Tribes of developing special Tribal migratory bird hunting regulation proposals, reviewing proposals, and publishing Tribal regulations as Federal regulations. This process will not apply to seasons for subsistence take of migratory birds in Alaska.

Title of Collection: Establishment of Annual Migratory Bird Hunting Seasons, 50 CFR part 20.

OMB Control Number: 1018–0171.

Form Numbers: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 52 (from State governments and Territories).

Total Estimated Number of Annual Responses: 78 (from 52 State and U.S. Territories, as well as 26 additional reports).

Estimated Completion Time per Response: Varies from 1 hour to 650 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 11,423.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Total Estimated Annual Non-hour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2024–05188 Filed 3–11–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX23DJ73UAC1000; OMB Control Number 1028–NEW]

Agency Information Collection Activities: Science and Data for Water-Hazards Response

AGENCY: U.S. Geological Survey, Department of Interior.

ACTION: Notice of Information Collection; request for comments

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before April 11, 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. Please provide a copy of your comments by mail to USGS, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192 or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW Science and Data for Water-Hazards in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this Information Collection Request (ICR), contact Jennifer Rapp by email at *jrapp@usgs.gov* or by telephone at 804–261–2635. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services

offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the 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 June 23, 2023 (88 FR 41124). 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 the agency might 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 personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: The United States is facing growing challenges related to water availability and quality due to shifting demographics, aging water-delivery infrastructure, the impacts of climate change, and increasing hazards risks, like those posed by floods and drought. Working with incomplete knowledge, managers must consider the needs of various demographic groups and economic sectors when making management decisions and responding to emergencies. To improve delivery of effective science to support decision-making, the USGS must adapt to meet the evolving needs of stakeholders in the water-hazard space. We will collect information regarding the decision-making process and scientific information and data needs to support daily, long-term, and emergency management decision-making. A lack of decision-support data within water institutions can lead to poor decision-making and outcomes that may increase the risk to life, property, and environmental health resulting from a hazard event. This information will support the delivery of appropriate data, in appropriate formats, at the right time for decision-making and emergency management. The information will guide USGS support of water-resource institutions, enhancing resilience in the face of the Nation's many water-resources challenges.

Title of Collection: Science and Data for Water-Hazards Response.

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: State and local water-resource managers and water-hazard responders; Tribal Nations and Tribal Serving Organizations; and non-governmental organizations and community groups that use water-hazard information.

State and Local Water Resource Managers and Responders:

Estimated Number of Annual Responses: 650.

Estimated Completion Time per Response: 1 hour.

Estimated Number of Annual Burden Hours: 650.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once per year.

Estimated Annual Nonhour Burden Cost: None.

Tribal Nations and Tribal Serving Organizations:

Estimated Number of Annual Responses: 200.

Estimated Completion Time per Response: 1 hour.

Estimated Number of Annual Burden Hours: 200.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once per year.

Estimated Annual Nonhour Burden Cost: None.

Non-governmental Organizations and Community Groups:

Estimated Number of Annual Responses: 150.

Estimated Completion Time per Response: 1 hour.

Estimated Number of Annual Burden Hours: 150.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once per year.

Estimated Annual Nonhour Burden Cost: None.

Total Estimated Number of Annual Responses: 1,000.

Total Estimated Number of Annual Burden Hours: 1,000.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor, nor is a person required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501 *et seq*).

Joseph Nielsen,

Director, Integrated Information Dissemination Division, USGS Water Resources Mission Area.

[FR Doc. 2024–05214 Filed 3–11–24; 8:45 am]

BILLING CODE 4388–11–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–NPS0037328; PPWONRADE1 PPMRSNR1Y:NM0000211P103601; OMB Control Number 1024–0254]

Agency Information Collection Activities; Comprehensive Survey of the American Public—Fourth Iteration

AGENCY: National Park Service, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS), are proposing to reinstate a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before April 11, 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 Review—Open for

Public Comments'' or by using the search function. Please provide a copy of your comments to Phadrea Ponds, NPS Information Collection Clearance Officer (ADIR–ICCO), 13461 Sunrise Valley Drive (MS–244) Herndon, VA 20171; or *phadrea_ponds@nps.gov* (email). Please reference Office of Management and Budget (OMB) Control Number 1024–0254 (CSAP4) in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this Information Collection Request (ICR), contact Bret Meldrum at *bret_meldrum@nps.gov (email)* or 970–267–7295 (telephone). Please reference OMB Control Number 1024–0254 (CSAP4) in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (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 November 10, 2022 (87 FR 67960). 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.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of response).

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Comprehensive Survey of the American Public (CSAP) is the only national information collection by the National Park Service (NPS) that describes visitors and non-visitors to units of the National Park System. Information on non-visitors, including their demographic characteristics and reasons for their non-visitation, is especially important in designing programs to reach underserved populations more effectively. The CSAP is administered every 5 years, a period determined to be long enough to identify important trends in key measures and to survey visitor and non-visitor perceptions, attitudes, behaviors, and knowledge related to the programs, services, and recreational opportunities offered by the NPS. Based on the strong mandate for social science research in support of park planning and management in the NPS Management Policies 2006 (Section 8.11.1, ''Social Science Studies''), this information collection will continue to provide high-quality data required to enhance the development of programs and resources within the NPS.

Title of Collection: Comprehensive Survey of the American Public—Fourth Iteration.

OMB Control Number: 1024–0254.

Form Number: None.

Type of Review: Reinstatement of a previously approved collection.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Respondents: 10,578. (3,500 household survey respondents, 7,078 non-response survey respondents).

Estimated Completion Time per Response: 25 minutes: household survey; 4 minutes: non-response survey.

Total Estimated Number of Annual Burden Hours: 1,930 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: one-time, annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collections Clearance Officer, National Park Service.

[FR Doc. 2024–05189 Filed 3–11–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–37587; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before March 2, 2024, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by March 27, 2024.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before March 2, 2024. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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.

Nominations submitted by State or Tribal Historic Preservation Officers

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

DISTRICT OF COLUMBIA

District of Columbia

Old Swedish Ambassador's Residence, 3900 Nebraska Avenue NW, Washington, SG100010177

KENTUCKY

Nelson County

Samuels, Wilson, House, 160 South St. Gregory Church Road, Samuels, SG100010189

LOUISIANA

East Baton Rouge Parish

Louisiana State University, Baton Rouge (Boundary Increase), Roughly bounded by West Chime Street, West Lakeshore Drive, Raphael Semmes Drive, Highland Road, S. Campus Drive, Dorothy Dix Drive, Minnie Fisk Drive, East Parker Boulevard, South Quad Drive, West Stadium Road, and Nicholson Drive, Baton Rouge, BC100010174

MICHIGAN

Kalamazoo County

Vicksburg Union Depot, 300 North Richardson Street, Vicksburg, SG100010197

MINNESOTA

St. Louis County

St. George Serbian Orthodox Church, 1216–104th Avenue West, Duluth, SG100010193

NEW JERSEY

Essex County

Weequahic High School, 279 Chancellor Avenue, Newark City, SG100010170

Hunterdon County

Bowne Station Road stone-arch bridge over tributary of the Alexauken Creek, Bowne Station Road over tributary of the Alexauken Creek, Delaware, SG100010172

Monmouth County

Dempsey Pump House, 55 Hamilton Avenue, Middletown Township, SG100010171

NEW YORK

Monroe County

Four Corners-Genesee Crossroads Historic District, Portions of Andrews, Aqueduct, E & W Broad, N & S Fitzhugh, Graves, E & W Main, Race, Saint Paul, State, N Water streets; N Plymouth Ave. & Exchange Blvd., Rochester, SG100010188

Richmond County

Richmond Town Historic District, Arthur Kill Rd, Richmond Rd, Clarke Ave, Center St, St. Patrick's Pl, Staten Island, SG100010190

NORTH CAROLINA

Henderson County

Samuel James and Jessie McCune Childs House, 105 Turley Falls Road, Hendersonville, SG100010192

McDowell County

Clinchfield Manufacturing Company Mill No. 2, 56 Branch Street, Marion, SG100010164

Warren County

Warrenton Historic District (Boundary Increase and Decrease), Roughly bounded by East Bute, Church. West Franklin, Halifax, North and South Hall, Harris, Hawkins, East Macon, North and South Main, and Warren Streets; the west ends of Fairview, Graham, and Rodwell Streets; Battle and Eaton Avenues; and Hazelwood Driv, Warrenton, BC100010195

OHIO

Union County

Oakdale Cemetery Historic District, 1290 W. Fifth Street, Marysville, SG100010203

VIRGINIA

Alexandria INDEPENDENT CITY

Bank of Potomac. Executive Office and Governor's Residence of the Restored Government of Virginia, 413–415 ½ Prince Street, Alexandria, SG100010198

Mathews County

Gwynn's Island Historic District, Generally including Route 223 (Cricket Hill Rd.), Route 633 (Old Ferry Road, N. Bay Haven Road). Route 740 (Hill Plantation Road), Gwynn, SG100010202

WEST VIRGINIA

Jefferson County

Rees-Daniel Fann, 330 Hidden Valley Drive, Kearneysville vicinity, SG100010180

Frederick Rosenberger Farm, 494 Harry Shirley Road, Kearneysville vicinity, SG100010181

Marion County

Amos Farmstead Historic District, 309 Gilboa Road, Fairmont vicinity, SG100010183

Morgan County

Saint Charles Catholic Mission Church, 153 Winchester Street, Paw Paw, SG100010184

Raleigh County

Wright-Hunter Cemetery, The intersection of Antonio Avenue and Lemp Lane, Beckley, SG100010187

Randolph County

Maplewood Cemetery, 301 Mapleview Drive, Elkins, SG100010186

Wayne County

Wayne County World War I Memorial, Southwest comer of North Court Street and Hendricks Street, Wayne, SG100010185

A request for removal has been made for the following resource(s):

FLORIDA

Hillsborough County

1314 South DeSoto Avenue of the Hyde Park Historic Districts, 1314 South DeSoto Avenue, (only), Tampa, OT85000454

MINNESOTA

Kanabec County

Zetterberg Company, (Kanabec County MRA), 630 E. Forest St., Mora, OT80002084

St. Louis County

Eveleth Manual Training Center, Roosevelt Ave., Eveleth, OT80004343

Stearns County

Freeport Roller Mill and Miller's House, (Stearns County MRA), Mary St., Freeport, OT82003043

Additional documentation has been received for the following resource(s):

LOUISIANA

East Baton Rouge Parish

Louisiana State University, Baton Rouge (Additional Documentation), Highland Rd., Baton Rouge, AD88001586

NORTH CAROLINA

Warren County

Warrenton Historic District (Additional Documentation), U.S. 401, Warrenton, AD76001347

TENNESSEE

White County

Indian Cave Petroglyphs (Additional Documentation), Address Restricted, Onward vicinity, AD78002649

VIRGINIA

Hanover County

Hickory Hill Slave and African American Cemetery (Additional Documentation), Providence Church Rd., Ashland vicinity, AD100005427

Loudoun County

Catoctin Creek Bridge (Additional Documentation), Rte. 673, N of Waterford, Waterford vicinity, AD74002136

Norfolk INDEPENDENT CITY

West Freemason Street Area Historic District (Additional Documentation), Both sides of Bute and Freemason Sts. between Elizabeth River, and York and Duke Sts., Norfolk (Independent City), AD72001512

WEST VIRGINIA

Kanawha County

Downtown Charleston Historic District (Additional Documentation), Roughly bounded by Washington St. E, Leon Sullivan Way, Knawha Blvd. and Summers St., Charleston, AD06000166

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2024–05174 Filed 3–11–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0009; DS63644000 DRT000000.CH7000 234D1113RT; OMB Control Number 1012–0008]

Agency Information Collection Activities; Collection of Monies Due to the Federal Government; and Processing Refund Requests Related to Overpayments Made to ONRR

AGENCY: Office of Natural Resources Revenue (''ONRR''), Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (''PRA''), ONRR is proposing to revise an information collection. Through this Information Collection Request (''ICR''), ONRR seeks to revise this collection and receive renewed authority to collect information necessary to cover cross-lease netting in the calculation of late-payment interest; a lessee's designation of designee for payment obligations; tribal permission for recoupment on Indian oil and gas leases; and refund requests for overpayments made to ONRR.

DATES: Interested persons are invited to submit comments on or before April 11, 2024.

ADDRESSES: All comment submissions must (1) reference ''OMB Control Number 1012–0008'' in the subject line; (2) be sent to ONRR before the close of the comment period listed under **DATES**; and (3) be sent using the following method:

Electronically via the Federal eRulemaking Portal: Please visit *https://www.regulations.gov.* In the Search Box, enter the Docket ID Number for this ICR renewal (''ONRR–2011–0009'') and click ''search'' to view the publications associated with the docket folder. Locate the document with an open comment period and click the ''Comment Now!'' button. Follow the prompts to submit your comment prior to the close of the comment period.

Docket: To access the docket folder to view the ICR **Federal Register** publications, go to *https://www.regulations.gov* and search ''ONRR–2011–0009'' to view renewal notices recently published in the **Federal Register**, publications associated with prior renewals, and applicable public comments received for this ICR. ONRR will make the comments submitted in response to this notice available for public viewing at *https://www.regulations.gov.*

OMB ICR Data: OMB also maintains information on ICR renewals and approvals. You may access this information at *https://www.reginfo.gov/public/do/PRASearch.* Please use the following instructions: Under the ''OMB Control Number'' heading enter ''1012–0008'' and click the ''Search'' button located at the bottom of the page. To view the ICR renewal or OMB approval status, click on the latest entry (based on the most recent date). On the ''View ICR—OIRA Conclusion'' page, check the box next to ''All'' to display all available ICR information provided by OMB.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mr. Christopher Davis, Financial Management, ONRR by email at *Christopher.Davis@onrr.gov* or by telephone at (303) 231–3977. To inquire about form ONRR–4425, please contact Aaron Lindquist, Data Solutioning and Technical Support, ONRR by email at *Aaron.Lindquist@onrr.gov* or by telephone at (303) 231–3020. To inquire about refund requests, please contact Thomas Anthony, Revenue, Reporting, and Compliance Management, ONRR by email at *Thomas.Anthony@onrr.gov* or by telephone at (303) 231–3708.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Pursuant to the PRA, 44 U.S.C. 3501, *et seq.,* and 5 CFR 1320.5, all information collections, as defined in 5 CFR 1320.3, require approval by OMB. ONRR may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of ONRR's continuing effort to reduce paperwork and respondent burdens, ONRR is inviting the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information in accordance with the PRA and 5 CFR 1320.8(d)(1). This helps ONRR to assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand ONRR's information collection requirements and provide the requested data in the desired format.

ONRR is especially interested in public comments addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of ONRR's 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.

ONRR published a notice, with a 60-day public comment period soliciting comments on this collection of information, in the **Federal Register** on December 1, 2023 (88 FR 83962).

ONRR reached out to members of industry soliciting comments for our information collection request renewal and received seven comments. Six members of industry provided comments agreeing with the content of this information collection, while one member of industry disagreed with the burden hour estimate. ONRR provided responses to each commenter accordingly.

Comments that you submit in response to this 30-day notice are a matter of public record. ONRR will include or summarize each comment in its request to OMB to approve this ICR. Before including your address, phone

number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask ONRR in your comment to withhold your personal identifying information from public review, ONRR cannot guarantee that it will be able to do so.

Abstract: (a) General Information: The Federal Oil and Gas Royalty Management Act of 1982 (''FOGRMA'') directs the Secretary of the Interior (''Secretary'') to ''establish a comprehensive inspection, collection and fiscal and production accounting and auditing system to provide the capability to accurately determine oil and gas royalties, interest, fines, penalties, fees, deposits, and other payments owed, and to collect and account for such amounts in a timely manner.'' 30 U.S.C. 1711. ONRR performs these and other mineral revenue management responsibilities for the Secretary. See U.S. Department of the Interior Departmental Manual, 112 DM 34.1 (Dec. 9, 2020). This ICR covers the burden hours associated with performing these responsibilities.

(b) Information Collections: This ICR concerns the following information.

(1) Cross-Lease Netting in Calculation of Late-Payment Interest: In calculating late-payment interest, ONRR allows a lessee to offset an overpayment made on a lease against an underpayment made on another lease if certain conditions are met. See 30 CFR 1218.42(a). ONRR refers to this offset as ''cross-lease netting.'' If a lessee asserts that interest is not owed due to cross-lease netting, it must provide information to ONRR showing that the conditions are met.

(2) Designation of Designee for Federal Oil and Gas Leases: FOGRMA allows a lessee to notify the Secretary in writing of its designation of ''a person to make all or part of the payments due under a lease on the lessee's behalf . . . in which event said designated person may, in its own name, pay, offset or credit monies, make adjustments, request and receive refunds and submit reports with respect to payments required by the lessee.'' See 30 U.S.C. 1712(a). ONRR specifies the information that a lessee must provide to designate a designee in 30 CFR 1218.52(a). A lessee must use form ONRR–4425, *Designation Form for Payment Responsibility,* to provide that information.

As discussed below, ONRR is modifying the form ONRR–4425 as part of this ICR renewal to be more consistent with FOGRMA and to better capture the information that a lessee is required to provide under 30 CFR 1218.52. The modifications do not expand the information collected or change the burden hours necessary to complete the form.

ONRR is modifying the title of the form from ''*Designation Form for Royalty Payment Responsibility*'' to ''*Designation Form for Payment Responsibility*'' because the form may be used for certain payment types other than royalty payments. See 30 U.S.C. 1712(a) and 30 CFR 1218.52(a)(3).

The current form ONRR–4425 has fields for specifying effective and termination dates for the designation. However, FOGRMA provides that a notice of designation, modification of designation, or termination of designation is effective upon receipt by the Secretary. See 30 U.S.C. 1702 (definition of ''designee''). ONRR therefore is removing the fields for a lessee to specify effective and termination dates and adding an instruction stating that a designation, modification of designation, or termination of designation is effective upon receipt by ONRR. ONRR is also adding a ''filing type'' field for the lessee to specify whether the form is being filed as an initial designation, a modification of a designation, or a termination of a designation.

The current form ONRR–4425 contains fields for a lessee to provide both the ONRR lease number and the leasing agency (Bureau of Land Management or Bureau of Safety and Environmental Enforcement) lease number for the designation. ONRR is modifying the form to require only the leasing agency number since ONRR's data systems can convert the leasing agency number to the ONRR lease number.

Section 1218.52(a)(6) requires the lessee to provide the name, address, and phone number of the individual to contact for the designee. However, the current form ONRR–4425 does not have a field for the lessee to supply this information. ONRR therefore is adding a field to the form for the lessee to provide this contact information if the designee is a company.

Though the current form ONRR–4425 contains fields for a lessee to specify whether it is the lessee of record or operating rights owner, it does not contain a place to provide its percentage of operating rights ownership in the lease, as required by § 1218.52(a)(4). ONRR therefore is modifying the form ONRR 4425 to include a field for a lessee to provide its percentage of operating rights ownership.

Section 1218.52(a)(10) requires a lessee to provide a copy of the written designation with the form ONRR–4425, reflecting the designee's acceptance of the designation. ONRR is modifying the form ONRR–4425 to remind the lessee of this requirement. ONRR also is modifying the form ONRR–4425 instructions to specify that a lessee may use this written designation to (i) add additional leases to the designation, (ii) specify product types for the designation, and (iii) specify its operating rights percentages in different areas covered by the lease if its operating rights ownership is not uniform throughout the lease. Finally, ONRR is removing any requirement to provide fax information.

(3) Tribal Permission for Recoupment on Indian Oil and Gas Leases: Pursuant to 30 CFR 1218.53(b), a payor may, with written permission authorized by tribal statute or resolution, recoup an overpayment against royalties or other revenues owed for the same production month under other leases for which that tribe is the lessor. See 30 CFR 1218.53(b). The payor must provide ONRR with a copy of that written permission. Id.

(4) Processing Refund Requests: FORGMA authorizes a Federal oil and gas lessee to request a refund for an overpayment in certain situations. See 30 U.S.C. 1721a(b). FOGRMA requires the lessee to supply information to support its refund request. Id. Additionally, ONRR collects banking information from the refund recipient in order to disburse the overpaid amount to the correct account if a refund is warranted.

Title: Collection of Monies Due the Federal Government; and Processing Refund Requests Related to Overpayments Made to ONRR.

OMB Control Number: 1012–0008.

Bureau Form Number: Form ONRR–4425.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Federal and Indian lessees.

Total Estimated Number of Annual Respondents: 170.

Total Estimated Number of Annual Responses: 170.

Total Estimated Number of Annual Burden Hours: 93 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: On occasion.

Total Estimated Annual Non-hour Burden Cost: We have identified no ''non-hour cost'' burden associated with this collection of information.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information

unless it displays a currently valid OMB control number.

The authority for this action is the PRA.

Howard Cantor,

Director, Office of Natural Resources Revenue.

[FR Doc. 2024–05212 Filed 3–11–24; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0012; DS63644000 DRT000000.CH7000 245D1113RT]

Major Portion Prices and Due Date for Additional Royalty Payments on Gas Produced From Indian Lands in Designated Areas That Are Not Associated With an Index Zone

AGENCY: Office of Natural Resources Revenue (ONRR), Interior.

ACTION: Notice.

SUMMARY: In accordance with regulations governing valuation of gas produced from Indian lands, ONRR is publishing this Notice in the **Federal Register** of the major portion prices applicable to calendar year 2022 and the date by which a lessee must pay any additional royalties due under major portion pricing.

DATES: The due date to pay additional royalties based on the major portion prices is May 31, 2024.

FOR FURTHER INFORMATION CONTACT: For questions regarding major portion prices, contact Robert Sudar, Market & Spatial Analytics, by telephone at (303) 231–3511 or email to *Robert.Sudar@onrr.gov.* For questions on reporting information, contact Tonisha Seader, Data Intake, Solutioning, and Coordination, by telephone at (303) 231–3478 or email to *Tonisha.Seader@onrr.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 30 CFR 1206.174(a)(4)(ii), ONRR must publish major portion prices for each designated area that is not associated with an index zone for each production month, as well as the due date to submit any additional royalty payments. If a lessee owes additional royalties, it must submit an amended form ONRR–2014, *Report of Sales and Royalty Remittance,* to ONRR and pay the additional royalties due by the due date. If a lessee fails to timely pay the additional royalties, late payment interest begins to accrue pursuant to 30 CFR 1218.54. The interest will accrue from the due date until ONRR receives payment.

The table below lists major portion prices for designated areas that are not associated with an index zone.

GAS MAJOR PORTION PRICES ($/MMBTU) FOR DESIGNATED AREAS NOT ASSOCIATED WITH AN INDEX ZONE

ONRR-designated areas	Jan 2022	Feb 2022	Mar 2022	Apr 2022
Fort Berthold Reservation	$5.45	$5.01	$3.99	$4.57
Fort Peck Reservation	6.54	8.04	4.02	5.09
Navajo Allotted Leases in the Navajo Reservation	5.95	4.83	4.28	5.76
Turtle Mountain Reservation	5.80	4.74	4.03	3.61
ONRR-designated areas	May 2022	Jun 2022	Jul 2022	Aug 2022
Fort Berthold Reservation	$6.39	$7.26	$5.53	$7.15
Fort Peck Reservation	6.63	7.81	5.68	7.64
Navajo Allotted Leases in the Navajo Reservation	6.81	8.30	6.35	8.39
Turtle Mountain Reservation	5.76	7.19	5.08	7.02
ONRR-designated areas	Sep 2022	Oct 2022	Nov 2022	Dec 2022
Fort Berthold Reservation	$6.23	$4.43	$4.17	$5.50
Fort Peck Reservation	7.69	4.84	4.23	6.65
Navajo Allotted Leases in the Navajo Reservation	8.40	5.38	6.02	14.53
Turtle Mountain Reservation	7.09	4.32	3.74	6.05

For information on how to report additional royalties due to major portion prices, please refer to ONRR's Dear Payor letter, dated December 1, 1999, which is available at *https://www.onrr.gov/reporter-letters/991201.pdf.*

Authorities: Indian Mineral Leasing Act, 25 U.S.C. 396a–g; Act of March 3, 1909, 25 U.S.C. 396; and the Indian Mineral Development Act of 1982, 25 U.S.C. 2103 *et seq.*

Howard Cantor,

Director, Office of Natural Resources Revenue.

[FR Doc. 2024–05199 Filed 3–11–24; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Benefit Accuracy Measurement Program

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Benefit Accuracy Measurement Program (BAM).'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by May 13, 2024.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Rhonda Cowie by telephone at (202) 693–3821 (this is not a toll-free number) or by email at *cowie.rhonda.m@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of

Unemployment Insurance, Room S–4520, 200 Constitution Avenue NW, Washington, DC 20210, by email at *cowie.rhonda.m@dol.gov,* or by Fax at (202) 693–3975.

FOR FURTHER INFORMATION CONTACT: Rhonda Cowie by telephone at (202) 693–3821 (this is not a toll-free number) or by email at *cowie.rhonda@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Since 1987, all State Workforce Agencies operating unemployment insurance (UI) programs, except the U.S. Virgin Islands, have been required by regulation at 20 CFR part 602 to operate BAM programs to assess the accuracy of their UI benefit payments in three programs: State UI, Unemployment Compensation for Federal Employees, and Unemployment Compensation for Ex-servicemembers. Beginning in 2001, BAM was modified to include the sampling and investigation of UI claims denied for monetary, separation, or nonseparation issues. The Payment Integrity Information Act of 2019 (31 U.S.C. 3352) and Section 303(a)(6) of the Social Security Act authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0245.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Extension without change.

Title of Collection: Benefit Accuracy Measurement Program.

Form: BAM State Operations Handbook (ETA Handbook 395, 5th edition).

OMB Control Number: OMB 1205–0245.

Affected Public: State Workforce Agencies (Primary), individuals, businesses, and not-for-profit institutions.

Estimated Number of Respondents: 181,634.

Frequency: Varies.

Total Estimated Annual Responses: 228,745.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 618,085 hours.

Total Estimated Annual Other Cost Burden: $0.

Brent Parton,

Principal Deputy Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2024–05148 Filed 3–11–24; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; BLS Labor Market Information Cooperative Agreement Application Package

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 April 11, 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 Labor Market Information (LMI) Cooperative Agreement application package includes all information needed by the State Workforce Agencies to apply for funds to assist them in operating one or more of the four LMI programs operated by the Bureau of Labor Statistics, and, once awarded, report on the status of obligation and expenditure of funds, as well as close out the Cooperative Agreement. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 8, 2024 (88 FRN 85658).

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: BLS Labor Market Information Cooperative Agreement Application Package.

OMB Control Number: 1220–0079.

Affected Public: State, Local and Tribal.

Total Estimated Number of Respondents: 54.

Total Estimated Number of Responses: 933.

Total Estimated Annual Time Burden: 756 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–05153 Filed 3–11–24; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; BLS Occupational Safety and Health Statistics Cooperative Agreement Application Package

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 April 12, 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 BLS signs cooperative agreements with States, and political subdivisions thereof, to assist them in developing and administering programs that deal with occupational safety and health statistics and to arrange through these agreements for research to further the objectives of the Occupational Safety and Health Act. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 8, 2023 (88 FRN 85657).

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: BLS Occupational Safety and Health Statistics Cooperative Agreement Application Package.

OMB Control Number: 1220–0149.

Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Respondents: 55.

Total Estimated Number of Responses: 493.

Total Estimated Annual Time Burden: 462 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–05242 Filed 3–11–24; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2024–0001]

Occupational Exposure to Beryllium and Beryllium Compounds in the Shipyard Sector; 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 Occupational Exposure to Beryllium and Beryllium Compounds in the Shipyard Sector.

DATES: Comments must be submitted (postmarked, sent, or received) by May 13, 2024.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://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 *http://www.regulations.gov.* Documents in the docket are listed in the *http://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–2024–0001) 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 purpose of these requirements is specified by the beryllium standards in the Shipyard Sector helps protect workers from harmful elements when exposed to permissible exposure limits of beryllium and beryllium compounds in the workplace. The following information collection requirements contained in the shipyard sector in the standard are described below.

Paragraph (d)(2) contains the performance option where the employer must assess the 8-hour time weighted average (TWA) exposure and the 15-minute short-term exposure for each employee on the basis of any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium. Employers do not have to conduct initial exposure monitoring if they rely on objective data that would satisfy the exposure assessment requirements contained in this standard. Paragraph (d)(3) says the employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area and the employer is required to do periodic monitoring when the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA permissible exposure limit (PEL), the employer must repeat such monitoring within six months of the most recent monitoring. Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL or above the short-term exposure limit (STEL), the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring. Paragraph (d)(4) requires the employer to reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

In paragraph (f)(1)(i) the employer is required to establish, implement, and maintain a written exposure control plan and what information and procedures are included in the plan. Paragraph (f)(1)(ii) requires the employer to review and evaluate the effectiveness of each written exposure control plan at least annually and update it, as necessary. Also, in paragraph (f)(1)(iii) the employer must make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

Paragraph (g)(2) requires the employer to provide respiratory protection for the selection and use of respirators, medical evaluations of employees required to use respirators, respirator fit testing procedures for tight-fitting respirators, and procedures for proper use of respirators in routine and reasonably foreseeable emergency situations.

Under paragraph (k)(1) the employer is required to make medical surveillance available at no cost to the employee, and at a reasonable time and place, to each employee who: (A) Is reasonably expected to be exposed at or above the action level for more than 30 days per year; (B) Shows signs or symptoms of chronic beryllium disease (CBD) or other beryllium-related health effects; or (C) Most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommended periodic medical surveillance.

In paragraph (k)(5) of medical surveillance, the employer is required to ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up beryllium lymphocyte proliferation test (BeLPT) required under paragraph (k)(3)(ii)(E) of this standard) and that the physician or other licensed health care professional (PLHCP) explains the results of the examination to the employee. The requirement for a written medical report ensures that the employee receives a record of all findings. In paragraph (k)(6) of medical surveillance the employer is required to obtain a written medical opinion from the licensed physician within 45 days of the medical examination and what must be contained in the written medical opinion. Under paragraph (k)(7) of medical surveillance, when being referred to the CBD Diagnostic Center, the employer is required to provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of: (A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or (B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center. The employer must ensure that the employee receives all written medical reports from the CBD diagnostic center that contains all the

information required in paragraph (k)(5)(i), (ii), (iv), and (v) and that the PLHCP explains the results of the examination to the employee within 30 days of the examination. Also, the employer is required to obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination and ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center within 30 days of any medical examination performed for that employee.

Under paragraph (l)(1) of medical removal, the employer is required to remove an employee that is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either: (i) the employee provides the employer with a written medical report indicating a confirmed positive finding or CBD diagnosis or a written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of the standard; or (ii) the employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of the standard.

In paragraph (m)(2) the employer is required to post warning signs at each approach to a regulated area. Paragraph (m)(3) requires the employer to label each bag and container of clothing, equipment, and materials contaminated with beryllium.

In paragraph (m)(4)(iv) the employer is required to make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

Under paragraph (n) recordkeeping, the employer is required to make and maintain records for the air monitoring data, objective data, medical surveillance, and training. Access to these records must be made available upon request for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance with the Record Access standard (29 CFR 1910.1020).

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 Occupational Exposure to Beryllium and Beryllium Compounds in the Shipyard Sector. The agency is requesting an adjustment decrease in burden from 6,609 hours to 2,565 hours, a difference of 4,044 hours. This decrease in burden is due to removing rule familiarization from this ICR and reducing the rate of non-compliance for employers.

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: Occupational Exposure to Beryllium and Beryllium Compounds Standard in the Shipyard Sector.

OMB Control Number: 1218–0272.

Affected Public: Business or other for-profits; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 696.

Number of Responses: 4,661.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 2,565.

Estimated Cost (Operation and Maintenance): $824,741.

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 *http://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–2024–0001). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at *http://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 *http://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 *http://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 March 7, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–05245 Filed 3–11–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2019–0010]

Occupational Exposure to Beryllium and Beryllium Compounds in General Industry; 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 Occupational Exposure to Beryllium and Beryllium Compounds in General Industry.

DATES: Comments must be submitted (postmarked, sent, or received) by May 13, 2024.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://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 *http://www.regulations.gov.* Documents in the docket are listed in the *http://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–2019–0010) 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 purpose of these requirements specified by the beryllium standards in General Industry help protect workers from harmful elements when exposed to permissible exposure limit (PEL) of beryllium and beryllium compounds in the workplace. The information collection requirements contained in the general industry standard are described below.

Paragraph (d)(2) contains the performance option where the employer must assess the 8-hour time weighted average (TWA) exposure and the 15-minute short-term exposure for each employee on the basis of any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium. Employers do not have to conduct initial exposure monitoring if they rely on objective data that would satisfy the exposure assessment requirements contained in this standard. Paragraph (d)(3) says the employer must perform initial monitoring to assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area and the employer is required to do periodic monitoring when the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring. Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL or above the short-term exposure limit (STEL), the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring. Paragraph (d)(4) requires the employer to reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

In paragraph (f)(1)(i) the employer is required to establish, implement, and maintain a written exposure control plan and what information and procedures are included in the plan. Paragraph (f)(1)(ii) requires the employer to review and evaluate the effectiveness of each written exposure control plan at least annually and update it as necessary. Also, in paragraph (f)(1)(iii) the employer must make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

Paragraph (g)(2) requires the employer to provide respiratory protection for the selection and use of respirators, medical evaluations of employees required to use respirators, respirator fit testing procedures for tight-fitting respirators, and procedures for proper use of respirators in routine and reasonably foreseeable emergency situations.

Paragraph (h)(3)(iii) requires the employer to inform in writing the persons or the business entities who launder, clean, or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard. This provision is intended to reduce exposure to beryllium for employees handling beryllium-contaminated materials by providing employers and employees handling these materials the information necessary to protect employees from beryllium exposure.

Under paragraph (k)(1) the employer is required to make medical surveillance available at no cost to the employee, and at a reasonable time and place, to each employee who: (A) Is reasonably expected to be exposed at or above the action level for more than 30 days per year; (B) Shows signs or symptoms of chronic beryllium disease (CBD) or other beryllium-related health effects; or (C) Is exposed to beryllium during an emergency; or (D) Most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommended periodic medical surveillance.

In paragraph (k)(5) of medical surveillance, the employer is required to ensure that the employee receives a written medical report from the licensed

physician within 45 days of the examination (including any follow-up beryllium lymphocyte proliferation test (BeLPT) required under paragraph (k)(3)(ii)(E) of this standard) and that the physician or other licensed health care professional (PLHCP) explains the results of the examination to the employee. The requirement for a written medical report ensures that the employee receives a record of all findings. In paragraph (k)(6) of medical surveillance the employer is required to obtain a written medical opinion from the licensed physician within 45 days of the medical examination and what must be contained in the written medical opinion. Under paragraph (k)(7) of medical surveillance, when being referred to the CBD Diagnostic Center, the employer is required to provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of: (A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or (B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD or recommending referral to a CBD diagnostic center. The employer must ensure that the employee receives all written medical reports from the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv), and (v), and that the PLHCP explains the results of the examination to the employee within 30 days of the examination. Also, the employer is required to obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination and ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center within 30 days of any medical examination performed for that employee.

Under paragraph (l)(1) of medical removal the employer is required to remove an employee that is eligible for medical removal if the employee works in a job with airborne exposure at or above the action level and either: (i) the employee provides the employer with a written medical report indicating a confirmed positive finding or CBD diagnosis or a written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of the standard; or (ii) the employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of the standard.

In paragraph (m)(2) the employer is required to post warning signs at each approach to a regulated area. Paragraph (m)(3) requires the employer to label each bag and container of clothing, equipment, and materials contaminated with beryllium.

In paragraph (m)(4)(iv) the employer is required to make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

Under paragraph (n) recordkeeping, the employer is required to make and maintain records for the air monitoring data, objective data, medical surveillance, and training. Access to these records must be made available upon request for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance with the Record Access standard (29 CFR 1910.1020).

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 Occupational Exposure to Beryllium and Beryllium Compounds in General Industry. The agency is requesting an adjustment decrease in burden from 82,822 to 32,587 hours, a difference of 50,235 hours. This decrease in burden is due to removing rule familiarization from this ICR and reducing the rate of non-compliance for employers.

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: Occupational Exposure to Beryllium and Beryllium Compounds Standard in General Industry.

OMB Control Number: 1218–0267.

Affected Public: Business or other for-profits; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 4,538.

Number of Responses: 52,956.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 32,587.

Estimated Cost (Operation and Maintenance): $6,365,761.

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 *http://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–2019–0010). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at *http://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 *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://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 March 5, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–05147 Filed 3–11–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2023–0012]

Federal Advisory Council on Occupational Safety and Health (FACOSH); Notice of Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of FACOSH meeting.

SUMMARY: The Federal Advisory Committee on Occupational Safety and Health (FACOSH) will meet April 18, 2024.

DATES: FACOSH will meet from 1 p.m.–4 p.m. ET, April 18, 2024, virtually via WebEx.

ADDRESSES:

Submission of comments and requests to speak: Submit comments and requests to speak at the FACOSH meeting by April 5, 2024, identified by the docket number for this **Federal Register** notice (Docket No. OSHA–2023–0012), using the following method:

Electronically: Comments and requests to speak, including attachments, must be submitted electronically at *www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Requests for special accommodations: Submit requests for special accommodations for this FACOSH meeting by April 5, 2024, to Ms. Lana Nieves, Directorate of Enforcement Programs, OSHA, U.S. Department of Labor; telephone: (202) 693–2128; email: *nieves.lana.a@dol.gov.*

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (Docket No. OSHA–2023–0012). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

Docket: To read or download documents in the public docket for this FACOSH meeting, go to *www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *www.regulations.gov.* 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.

Participation in the FACOSH meeting: Members of the public may register to attend the FACOSH meeting by going to the website: *https://usdolee.webex.com/usdolee/j.php?MTID=m25c3ee95bbf132dacfd3723e80967bb0.*
VoIP or dial: 877–465–7975
Access code: 2760 654 2774
Meeting password: Welcome!24
(93526631 from phones)

However, any participation by the public will be in listen-only mode.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information: Ms. Lana Nieves, Supervisor, OSHA Office of Federal Agency Programs; telephone (202) 693–2128; email: *ofap@dol.gov.*

Copies of this ***Federal Register*** *document:* Electronic copies of this **Federal Register** document are available at *http://www.regulations.gov.* This document, as well as news releases and other relevant information are also available on the OSHA web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FACOSH is authorized to advise the Secretary of Labor (Secretary) on all matters relating to the occupational safety and health of Federal employees (Occupational Safety and Health Act of 1970 (29 U.S.C. 668), 5 U.S.C. 7902, Executive Orders 12196 and 14109). This includes providing advice on how to reduce and keep to a minimum the number of injuries and illnesses in the Federal workforce and how to encourage the establishment and maintenance of effective occupational safety and health programs in each Federal agency.

II. Meeting Information

FACOSH Meeting

FACOSH will meet from 1 p.m. to 4 p.m., ET, Thursday, April 18, 2024. The meeting is open to the public.

Meeting agenda: The tentative agenda for this meeting includes:

- Assistant Secretary's Agency Update and Remarks;
- Update from FACOSH's Subcommittee on Identification of Best Practices and Lessons Learned;
- National Institute for Occupational Safety and Health's Total Worker Health, New Recovery Toolkit, Recovery-Ready Workplace Resources;
- Health and Human Services and General Services Administration's Guidelines for Naloxone in Federal Facilities; and
- Department of Interior's Implementation of Carry and Use of Naloxone.

Member and public attendance at the FACOSH meeting will be virtual only. The public can listen in to the FACOSH meeting at: *https://usdolee.webex.com/weblink/register/r9d1ba59530df355b6fc569206b6b9eaa.*

In addition, meeting information will be posted to Office of Federal Agency's website at: *https://www.osha.gov/advisorycommittee/facosh.*

Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice under the authority granted by section 19 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 668), 5 U.S.C. 7902, the Federal Advisory Committee Act (5 U.S.C. 10), Executive Order 12196 and 14109, Secretary of Labor's Order 8–2020 (85 FR 58393, 9/18/2020), 29 CFR part 1960 (Basic Program Elements of for Federal Employee Occupational Safety and Health Programs), and 41 CFR part 102–3.

Signed at Washington, DC.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–05150 Filed 3–11–24; 8:45 am]

BILLING CODE 4510–26–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2023–107]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 14, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2023–107; *Filing Title:* USPS Notice of Amendment to Priority Mail, First-Class Package Service & Parcel Select Service Contract 6, Filed Under Seal; *Filing Acceptance Date:* March 6, 2024; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* March 14, 2024.

This Notice will be published in the **Federal Register**.

Mallory S. Richards,

Federal Register Liaison.

[FR Doc. 2024–05187 Filed 3–11–24; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99681; File No. SR–ISE–2024–03]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Options on iShares Bitcoin Trust

March 6, 2024.

On January 9, 2024, Nasdaq ISE, LLC filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade options on iShares Bitcoin Trust. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] The Commission has received five comments on the proposed rule change.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 10, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates April 24, 2024 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–ISE–2024–03).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–05149 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99396 (January 19, 2024), 89 FR 5047.

[4] Comments are available at: *https://www.sec.gov/comments/sr-ise-2024-03/srise202403.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99680; File No. SR–CBOE–2024–005]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Permit Cboe To List and Trade Options on ETPs That Hold Bitcoin

March 6, 2024.

On January 5, 2024, Cboe Exchange, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade options on ETPs that hold bitcoin. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 10, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates April 24, 2024 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CBOE–2024–005).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–05155 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99684; File No. SR–MIAX–2024–03]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Exchange-Traded Fund Shares That Represent Interests in a Trust That Holds Bitcoin

March 6, 2024.

On January 12, 2024, Miami International Securities Exchange LLC filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade options on Exchange-Traded Fund Shares that represent interests in a trust that holds bitcoin. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 10, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates April 24, 2024 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–MIAX–2024–03).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–05156 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99682; File No. SR–PEARL–2024–03]

Self-Regulatory Organizations; MIAX PEARL LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Exchange-Traded Fund Shares That Represent Interests in a Trust That Holds Bitcoin

March 6, 2024.

On January 12, 2024, MIAX PEARL LLC filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade options on Exchange-Traded Fund Shares that represent interests in a trust that holds bitcoin. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99395 (January 19, 2024), 89 FR 5075.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99397 (January 19, 2024), 89 FR 5079.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99394 (January 19, 2024), 89 FR 5058.

[4] 15 U.S.C. 78s(b)(2).

proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 10, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates April 24, 2024 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–PEARL–2024–03).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–05151 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99683; File No. SR–NYSEARCA–2024–06]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Rule 5.3–O To Permit the Listing and Trading of Options on Commodity-Based Trust Shares

March 6, 2024.

On January 16, 2024, NYSE Arca, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade options on Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] The Commission has received one comment on the proposed rule change.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 10, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates April 24, 2024 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEARCA–2024–06).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–05152 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99685; File No. SR–NYSENAT–2024–05]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Rule 7.31

March 6, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on February 26, 2024, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Rule 7.31 regarding Primary Pegged Orders. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 regarding Primary Pegged Orders.

Rule 7.31(h) defines a Pegged Order as a Limit Order that does not route with a working price that is pegged to a dynamic reference price. If the designated reference price is higher (lower) than the limit price of a Pegged Order to buy (sell), the working price will be the limit price of the order.

Rule 7.31(h)(2) defines a Primary Pegged Order as a Pegged Order to buy (sell) with a working price that is pegged to the PBB (PBO), with no offset allowed. A Primary Pegged Order to buy (sell) will be rejected on arrival, or cancelled when resting, if there is no PBB (PBO) against which to peg.

Rule 7.31(h)(2)(A) currently provides that a Primary Pegged Order must include a minimum of one round lot displayed. Rule 7.31(h)(2)(A) further provides that the working price of a Primary Pegged Order equals the display price, the display quantity is ranked Priority 2—Display Orders, and the reserve interest is ranked Priority 3—Non-Display Orders.

Rule 7.31(h)(2)(B) provides that a Primary Pegged Order will be rejected if the PBBO is locked or crossed. If the

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99398 (January 19, 2024), 89 FR 5029.

[4] Comments are available at: *https://www.sec.gov/comments/sr-nysearca-2024-06/srnysearca202406.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

PBBO is locked or crossed when the display quantity of a Primary Pegged Reserve Order is replenished, the entire order will be cancelled. If after arrival, the PBBO becomes locked or crossed, the Primary Pegged Order will wait for a PBBO that is not locked or crossed before the display and working price are adjusted and remains eligible to trade at its current working price.

The Exchange proposes to modify Rule 7.31(h)(2)(A) to permit Primary Pegged Orders to be entered in any size and thus proposes to eliminate rule text currently providing that a Primary Pegged Order must include a minimum of one round lot displayed. The Exchange believes that requiring Primary Pegged Orders to be entered in round lots is unnecessary and that providing ETP Holders with the option to enter Primary Pegged Orders in odd lots could increase liquidity and enhance opportunities for order execution on the Exchange. The Exchange notes that permitting odd-lot order quantities is not novel on the Exchange or other cash equity exchanges and believes that this proposed change would align the Exchange's handling of Primary Pegged Orders with the treatment of equivalent order types on other cash equity exchanges.[4]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update, which, subject to effectiveness of this proposed rule change, will be in the first quarter of 2024.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5),[6] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest because it would provide ETP Holders with the option to enter Primary Pegged Orders in odd-lot sized orders, which could encourage order flow to the Exchange and promote opportunities for order execution on the Exchange, to the benefit of all market participants. The Exchange notes that the proposed change would not otherwise impact the operation of Primary Pegged Orders as provided under current Exchange rules. The Exchange also believes that the proposed change would align Exchange rules with the treatment of orders analogous to Primary Pegged Orders on other cash equity exchanges, thereby removing impediments to, and perfecting the mechanism of, a free and open market and a national market system.[7]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the Exchange believes the proposed rule change would allow the Exchange to accept Primary Pegged Orders of any size and align the Exchange's handling of such orders with other cash equity exchanges' handling of similar order types,[8] thereby promoting competition among exchanges by offering ETP Holders options available on other cash equity exchanges. The Exchange also believes that, to the extent the proposed change would increase opportunities for order execution, the proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6)[12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to allow it to accept Primary Pegged Orders of any size as soon as the technology associated with the proposed change is available. The Exchange states that the proposal raises no novel issues and that waiver of the operative delay would allow the Exchange to more expeditiously offer increased flexibility to member organizations and promote additional trading opportunities for all market participants. The Commission finds that, because the proposal does not change the operation of Primary Pegged Orders, other than to expand their use to odd-lot orders, waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[14]

[4] *See, e.g.,* Members Exchange Rules 11.8(c)(2) (providing that a Primary Peg Order may be entered as an odd lot, round lot, or mixed lot). The Exchange also notes that the rules of the Nasdaq Stock Market LLC (''Nasdaq''), Cboe BZX Exchange, Inc. (''BZX''), and Cboe BYX Exchange, Inc. (''BYX'') appear to permit orders, including orders analogous to Primary Pegged Orders, to be entered in any size. *See* Nasdaq Rule 4703(b) (providing that an order may be entered in any whole share size, except as otherwise provided); BZX Rule 11.2 (providing that orders are eligible for odd-lot, round-lot, and mixed-lot executions unless otherwise indicated); BYX Rule 11.2 (same).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *See* note 4, *supra.*

[8] *Id.*

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on

Continued

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2024–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2024–05. 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–NYSENAT–2024–05 and should be submitted on or before April 2, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–05154 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P

efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. EP 670 (Sub-No. 1)]

Notice of Rail Energy Transportation Advisory Committee Meeting

AGENCY: Surface Transportation Board.

ACTION: Notice of Rail Energy Transportation Advisory Committee meeting.

SUMMARY: Notice is hereby given of a meeting of the Rail Energy Transportation Advisory Committee (RETAC), pursuant to the Federal Advisory Committee Act.

DATES: The meeting will be held on Wednesday, April 17, 2024, at 9:00 a.m. E.T.

ADDRESSES: The meeting will be held at the Surface Transportation Board headquarters at 395 E Street SW, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Kristen Nunnally at (202) 245–0312 or *Kristen.Nunnally@stb.gov.* If you require an accommodation under the Americans with Disabilities Act for this meeting, please call (202) 245–0245 by April 3, 2024.

SUPPLEMENTARY INFORMATION: RETAC was formed in 2007 to provide advice and guidance to the Surface Transportation Board (Board or STB), and to serve as a forum for discussion of emerging issues related to the transportation of energy resources by rail. *Establishment of a Rail Energy Transp. Advisory Comm.,* EP 670 (STB served July 17, 2007). The purpose of this meeting is to facilitate discussions regarding issues including rail service, infrastructure planning and development, and effective coordination among suppliers, rail carriers, and users of energy resources. Potential agenda items for this meeting include a rail performance measures review, industry segment updates by RETAC members, and a roundtable discussion.

The meeting, which is open to the public, will be conducted in accordance with the Federal Advisory Committee Act, 5 U.S.C. app. 2; Federal Advisory Committee Management regulations, 41 CFR part 102–3; RETAC's charter; and Board procedures. Further communications about this meeting may be announced through the Board's website at *www.stb.gov.*

Written Comments: Members of the public may submit written comments to RETAC at any time. Comments should be addressed to RETAC, c/o Kristen Nunnally, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001 or *Kristen.Nunnally@stb.gov.* Please submit any comments for review at the April 17, 2024, meeting by April 15, 2024, if possible.

Authority: 49 U.S.C. 1321, 11101, and 11121.

Decided: March 6, 2024.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2024–05167 Filed 3–11–24; 8:45 am]

BILLING CODE 4915–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Approvals by Rule for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: February 1–29, 2024.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.gov.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule

process set forth in 18 CFR 806.22 (f) for the time period specified above.

Water Source Approval—Issued Under 18 CFR § 806.22(f)

1. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Hurley Drilling Pad #1; ABR–201201040.R2; Cherry Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 5, 2024.

2. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Manahan; ABR–201201036.R2; Albany Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 5, 2024.

3. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Messersmith; ABR–201201037.R2; Wilmot Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 5, 2024.

4. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: SGL289C; ABR–201201034.R2; West Burlington Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 5, 2024.

5. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Warburton; ABR–201201033.R2; Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 5, 2024.

6. RENEWAL—Seneca Resources Company, LLC; Pad ID: My TB INV LLC 6076; ABR–201702001.R1; Deerfield Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 8, 2024.

7. RENEWAL—Seneca Resources Company, LLC; Pad ID: Rich Valley Pad F; ABR–201402002.R2; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 8, 2024.

8. RENEWAL—Seneca Resources Company, LLC; Pad ID: Rich Valley Pad G; ABR–201402001.R2; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 8, 2024.

9. RENEWAL—Range Resources—Appalachia, LLC; Pad ID: Cornwall 1H–5H; ABR–201402006.R2; Lewis Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 13, 2024.

10. RENEWAL—Repsol Oil & Gas USA, LLC; Pad ID: COREY (07 089) J; ABR–201402008.R2; Choconut Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 13, 2024.

11. RENEWAL—Repsol Oil & Gas USA, LLC; Pad ID: KROPIEWNICKI (07 038) J; ABR–201402004.R2; Apolacon Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 13, 2024.

12. RENEWAL—Repsol Oil & Gas USA, LLC; Pad ID: YORK (07 088) R; ABR–201402005.R2; Little Meadows Borough, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 13, 2024.

13. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Ferraro; ABR–201202007.R2; Terry Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 14, 2024.

14. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Makayla; ABR–201202008.R2; Wilmot Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 14, 2024.

15. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Schlapfer; ABR–201202006.R2; Albany Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 14, 2024.

16. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Moyer; ABR–201202019.R2; Overton Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 19, 2024.

17. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Yadpad; ABR–201202020.R2; Wilmot Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 19, 2024.

18. RENEWAL—Coterra Energy Inc.; Pad ID: Jeffers Farms P2; ABR–201702002.R1; Harford Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: February 19, 2024.

19. RENEWAL—Repsol Oil & Gas USA, LLC; Pad ID: CAPRIO (07 077) S; ABR–201402011.R2; Apolacon Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 19, 2024.

20. RENEWAL—SWN Production Company, LLC; Pad ID: RU–65–LEONARD–PAD; ABR–201402010.R2; Jackson Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: February 19, 2024.

21. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: HEMLOCK RIDGE ESTATES PAD; ABR–201902003.R1; McNett Township, Lycoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 26, 2024.

22. RENEWAL—Coterra Energy Inc.; Pad ID: MakoskyT P1; ABR–201402012.R2; Brooklyn Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: February 26, 2024.

23. RENEWAL—Coterra Energy Inc.; Pad ID: MillardK P1; ABR–201402013.R2; Jessup Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: February 26, 2024.

24. Repsol Oil & Gas USA, LLC; Pad ID: DECRISTO (01–128); ABR–202402002; Sullivan Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 26, 2024.

25. RENEWAL—Chesapeake Appalachia, L.L.C.; Pad ID: Muzzy Drilling Pad #1; ABR–201202027.R2; Ulster Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: February 29, 2024.

26. RENEWAL—Seneca Resources Company, LLC; Pad ID: Kreitzer 505; ABR–201202030.R2; Rutland Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 29, 2024.

27. Repsol Oil & Gas USA, LLC; Pad ID: UPHAM (05–093); ABR–202402001; Pike Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 29, 2024.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: March 7, 2024.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2024–05195 Filed 3–11–24; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

General Permit Notice

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Grandfathering Registration for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: February 1–29, 2024.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.gov*. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists General Permits for projects

described below, pursuant to 18 CFR part 806.17©(4), for the time period specified above:

1. Cherokee Pharmaceuticals LLC, General Permit Approval of Coverage No. GP–01–20240204, Riverside Borough, Northumberland County, Pa.; groundwater remediation system withdrawal approved up to 0.600 mgd (30-day average); Approval Date: February 9, 2024.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: March 7, 2024.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2024–05196 Filed 3–11–24; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Minor Modifications

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the minor modifications approved for a previously approved project by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: January 1, 2024–February 29, 2024.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists previously approved projects, receiving approval of minor modifications, described below, pursuant to 18 CFR 806.18 or to Commission Resolution Nos. 2013–11 and 2015–06 for the time period specified above.

1. Koppers Inc., Docket No. 20231209, Clinton Township, Lycoming County, Pa.; correction in Section 3 of source name; Correction Issue Date: January 9, 2024.

2. Dart Container Corporation of Pennsylvania, Docket No. 20040910–3, Upper Leacock Township, Lancaster County, Pa.; modification approval to add public water supply (Upper Leacock Township Municipal Authority) as an additional source of consumptive use, with no changes to existing quantities; Approval Date: February 23, 2024.

3. Murry Development Corporation—Crossgates Golf Club, Docket No. 20231223, Manor Township and Millersville Borough, Lancaster County, Pa.; modification approval to change the consumptive use mitigation method; Approval Date: February 29, 2024.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: March 7, 2024.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2024–05197 Filed 3–11–24; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2023–0040]

Request for Information on the Use of Manufactured Products in Highway Projects

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice; request for information (RFI).

SUMMARY: On March 17, 2023, FHWA published a request for comments on its existing general applicability waiver for manufactured products under its Buy America waiver authorities. Following the review and consideration of comments, FHWA is proposing to discontinue the waiver. The FHWA is also proposing standards for applying Buy America requirements to manufactured products should the waiver be discontinued. To ensure the continued effective implementation of FHWA programs that would be subject to new requirements for manufactured products, FHWA is seeking additional information on the domestic availability of specific manufactured products commonly used in FHWA-funded projects. To ensure the Agency has the most comprehensive and current information available on the domestic market for manufactured products used in FHWA infrastructure projects, FHWA is especially interested in comments detailing domestic materials sourcing, market readiness, timeliness of product supply, and other considerations.

DATES: Comments must be received on or before May 13, 2024. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit comments by only one of the following means:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590;
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329;
- *Instructions:* You must include the agency name and docket number at the beginning of your comments. Except as described below under the heading ''Confidential Business Information,'' all submissions received, including any personal information provided, will be posted without change or alteration to *www.regulations.gov.* For more information, you may review the U.S. Department of Transportation's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Brian Hogge, FHWA Office of Infrastructure, (202) 366–1562, or via email at *Brian.Hogge@dot.gov.* For legal questions, please contact Mr. David Serody, FHWA Office of the Chief Counsel, (202) 366–4241, or via email at *David.Serody@dot.gov.* Office hours for FHWA are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

A copy of this notice, all comments received on this notice, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval assistance and guidelines are also available at *www.regulations.gov.* An electronic copy of this document also may be downloaded from the Office of the Federal Register's website at: *www.FederalRegister.gov* and the U.S. Government Publishing Office's website at: *www.GovInfo.gov.*

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial

information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this 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 this notice, it is important that you clearly designate the submitted comments as CBI.

You may ask FHWA to give confidential treatment to information you give to the Agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send FHWA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. The FHWA will protect confidential information complying with these requirements to the extent required under applicable law. If DOT receives a FOIA request for the information that the applicant has marked in accordance with this notice, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.29. Only information that is marked in accordance with this notice and ultimately determined to be exempt from disclosure under FOIA and 49 CFR 7.29 will not be released to a requester or placed in the public docket of this notice. Submissions containing CBI should be sent to: Mr. Brian Hogge, FHWA, 1200 New Jersey Avenue SE, HICP–20, Washington, DC 20590 via mail or *brian.hogge@dot.gov* via email. Any comment submissions that FHWA receives that are not specifically designated as CBI will be placed in the public docket for this matter.

Background

Section 313(a) of Title 23, U.S.C. requires that all steel, iron, and manufactured products used in FHWA-funded projects be produced in the United States. In 1983, FHWA issued a public interest waiver of general applicability of FHWA's Buy America requirement for manufactured products, known as the Manufactured Products General Waiver. *See* 48 FR 1946 (Jan. 17, 1983); 48 FR 53099 (Nov. 25, 1983). Based on the Manufactured Products General Waiver, FHWA does not currently apply its Buy America requirements to manufactured products except for predominantly iron or steel manufactured products and predominantly iron or steel components of manufactured products, which must comply with FHWA's existing Buy America requirements for iron or steel. For all predominantly iron or steel materials, products, or components delivered to a project site for permanent incorporation into a highway project using Title 23, U.S.C. funds, all manufacturing processes, including applications of a coating, must occur in the United States. *See* 23 CFR 635.410. In addition, FHWA's Buy America requirement applies to all contracts, regardless of the funding source, of any contract within the scope of a determination under the National Environmental Policy Act involves an obligation of Title 23, U.S.C. funds. *See* 23 U.S.C. 313(h).

On November 15, 2021, the President signed the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act (Pub. L. 117–58) into law. The BIL includes the Build America, Buy America (BABA) Act. BIL, div. G §§ 70901–53. Section 70914(d) of BABA requires Federal Agencies to review existing general applicability waivers of Buy America requirements by publishing in the **Federal Register** a notice that: (i) describes the justification for the general applicability waiver; and (ii) requests public comments for a period of not less than 30 days on the continued need for the general applicability waiver.

On March 17, 2023, pursuant to § 70914(d) of BABA, FHWA published a Request for Comment (RFC) on the Manufactured Products General Waiver in the **Federal Register** (''Manufactured Products RFC''). *See* 88 FR 16517. The FHWA received 9,496 comments in response to the 12 questions that were posed. Based on the contents of that review, and after considering the President's policy, as embodied in Executive Order 14005, ''Ensuring the Future Is Made in All of America by All of America's Workers,'' to maximize the use of goods, products, and materials produced in the United States; the intent of Congress, as expressed in BABA's preference against general applicability waivers; the purpose and goals of domestic content procurement preferences and waivers; and FHWA's original rationale for issuing the Manufactured Products General Waiver compared to the current domestic manufacturing situation, FHWA is proposing to discontinue the Manufactured Products General Waiver; at the same time, FHWA is issuing a notice of proposed rulemaking (NPRM) to propose the standards for when a manufactured product will be considered to be ''produced in the United States'' and therefore be Buy America-compliant (''Manufactured Products NPRM'').[1] Interested parties should refer to the NPRM for the reasons and discussion concerning the proposed discontinuance of the waiver and proposed regulations.

As further explained in the NPRM, the proposed Buy America requirements for manufactured products mirror the requirements for manufactured products to be produced under § 70912(6)(B) of BABA and are substantially aligned with the applicable definitions and requirements for manufactured products in the Office of Management and Budget's guidance implementing BABA at 2 CFR part 184. To be ''produced in the United States,'' a product would need to be manufactured in the United States and have the cost of components of the manufactured product that are mined, produced, or manufactured in the United States be greater than 55 percent of the total cost of all components of the manufactured product.[2]

As stated in the Manufactured Products NPRM, FHWA recognizes that certain types of manufactured products incorporated into FHWA-funded projects may not be currently available from domestic sources. To identify the manufactured products to which applying a Buy America requirement for manufactured products could cause those products to be rendered unavailable for FHWA-funded projects, FHWA is seeking additional information and documentation on products that are commonly procured or are expected to be procured using FHWA financial assistance that may not be currently manufactured domestically or do not otherwise meet the 55 percent domestic content standard being proposed in the NPRM. To ensure FHWA has the most comprehensive and current information available on the domestic market for manufactured products used in FHWA projects, FHWA is specifically seeking detailed comments on domestic materials sourcing, market readiness, pricing, other product supply

[1] Buy America Requirements for Manufactured Products, RIN 2125–AG13, Docket No. FHWA–2023–0037.

[2] Under FHWA's proposed requirements, manufactured products would not be subject to any other Buy America requirement or domestic content procurement preference, with two exceptions. First, all iron or steel components of precast concrete products that are classified as manufactured products would need to meet FHWA's existing Buy America requirements for iron or steel. Second, for iron or steel cabinets or other enclosures of intelligence transportation systems (ITS) and other electronic hardware systems that are installed in the highway right-of-way or other real property and classified as manufactured products, such iron or steel cabinets and other enclosures would also need to meet FHWA's existing Buy America requirements for iron or steel.

considerations, and whether specific manufactured products or their components are manufactured in the United States for manufactured products used in projects that receive FHWA financial assistance.

The Manufactured Products RFC posed the following questions to manufactured product suppliers:

4. With respect to domestic manufacturers of products previously procured or expected to be procured using FHWA financial assistance, do you expect to expand your domestic manufacturing based on the increase in demand created by recent Federal investments? If so, by how much and over what time period? If applicable, what is the timeline to bring online additional capacity compliant with BABA?

In response to question 4, manufacturers who responded appeared evenly split between expecting to expand domestic manufacturing and not to expand domestic manufacturing. Of those who were not planning to expand, the reasons for not expanding included having existing unused capacity, a lack of sufficient domestic demand, and the high relative costs of expanding. Several manufacturers were still evaluating expanding domestic manufacturing while two others reported either already expanding capacity or that they are currently producing products meeting the standard for manufactured products under BABA. For those who expected that they would need to expand their domestic manufacturing, the timeline to increase domestic capacity was either stated to be multiple years or an unknown amount of time.

Commenters were also asked in the Manufactured Products RFC:

Are there specific types of manufactured products that are widely used on Federal-aid highway projects for which a large portion of the components are known to not be produced in the United States or not produced in sufficient quantities? If so, what are those components, what manufacturer produces them, and where are they primarily produced? What are the obstacles to having those components produced in the United States? Please provide data to support your comment.

In response, more than two-thirds of commenters indicated there are frequently used manufactured products and components of manufactured products that are currently not widely available from domestic producers. Some of the most frequently mentioned products and components included the following: assembled electronics; electronic components; lighting systems and LEDs; ITS, and reflective materials. Commenters noted obstacles to having those components produced in the United States, which included that components and raw materials are not readily available in the United States, needing time for U.S. production to scale up, low demand and thus low incentives for domestic production, potential unforeseen shortages, subsidized production in other countries, the likelihood of more expensive production in the United States, and intellectual property constraints.

The FHWA is interested in promptly obtaining more information on the availability of manufactured products that can meet the standard proposed in the Manufactured Products NPRM in order to assess if sufficient quantities of products are currently available to comply with the proposed requirements or whether sufficient products would be available in the future, and if so, when. The FHWA is also interested in obtaining more information on the cost of manufactured products that can meet the standard proposed in the Manufactured Products NPRM, relative to manufactured products available from foreign or non-compliant domestic sources.

On August 16, 2023, DOT issued a ''Waiver of Buy America Requirements for De Minimis Costs and Small Grants'' (De Minimis and Small Grants Waiver). 88 FR 55817. The De Minimis and Small Grants Waiver covers the application of Buy America requirements to products under a single financial assistance award for which (1) the total value of non-compliant products is no more than the lesser of $1,000,000 or 5 percent of total applicable costs for the project; or (2) the amount of Federal financial assistance applied to the project, through awards or subawards, is below $500,000. The FHWA's statutory Buy America requirements for manufactured products are covered under the scope of the De Minimis and Small Grants waiver, so it would apply to manufactured products covered by that waiver even if the Manufactured Products General Waiver were to be rescinded.

Request for Comments and Information

The FHWA requests information from the public on the following products or categories of products identified in responses to the Manufactured Products RFC as being broadly unavailable from Buy America-compliant sources: [3]

- Retroreflective sheeting
- LED lamps/lighting systems
- Utility products
- ITS hardware
- Traffic signals and controllers
- Traffic cameras
- Changeable message signs
- Vehicle detection equipment.

The FHWA is also interested in receiving information on other manufactured products commonly used on FHWA-assisted projects that are not listed above, but which the commenter believes may not be available from domestic sources or may be available only at higher prices than from foreign sources or from non-compliant domestic sources. In identifying such products, note that some manufactured items may be classified as iron or steel products or as construction materials, consistent with the definitions of those items found in the Manufactured Products NPRM and in 2 CFR part 184.

For each of these products, and based on your understanding of the Manufactured Product NPRM's proposed requirements, FHWA is requesting information under five general topic areas: (1) domestic materials sourcing and manufacturing; (2) market readiness; (3) delivery lead times; (4) pricing; and (5) other considerations.

When providing this information, FHWA requests that all respondents clearly specify the products for which you are providing responses. When providing information on other manufactured products commonly used on FHWA-assisted products that are not specifically listed above, please provide a detailed description of the product.

1. Domestic Materials Sourcing and Manufacturing

a. For each of the products or categories of products you identified above, please specify whether the product meets the Manufactured Product NPRM's proposed standards for being considered ''produced in the United States,'' as described above. (Yes or No).

b. If you answered ''Yes'' to Topic 1(a), to the best of your knowledge:

i. Please identify all manufacturers that can either meet the Manufactured Products NPRM's proposed requirements or can currently manufacture products or categories of products you specified in the United States. For products that meet the condition of being manufactured in the

[3] Commenters on the Manufactured Products RFC also cited certain other products that FHWA believes would likely be considered construction materials under the standards of 2 CFR part 184 and would thus not be subject to the requirements for manufactured products that are being proposed in the NPRM.

United States, please identify the manufacturing location and percentage of components manufactured in the United States, as calculated by cost of components (if known).

ii. What is the current production capacity of the products that can meet the Manufactured Products NPRM's proposed requirements?

iii. What is the anticipated growth in capacity to produce products that are compliant with the Manufactured Products NPRM's proposed requirements over the next 5 years? Please explain.

iv. For products able to meet the Manufactured Products NPRM's proposed requirements, what is the estimated lead time from purchase order to delivery to the project site? Has this lead time increased or decreased in recent years?

c. If you answered ''No'' to Topic 1(a):

i. What actions are manufacturers taking or could take to increase the manufacturing of products that will meet the Manufactured Products NPRM's proposed requirements?

ii. What additional support or incentives (*e.g.,* financial, rulemaking certainty) are needed to ensure that a sufficient supply of products that meet the Manufactured Products NPRM's proposed requirements will be available to meet the demand for compliant products on Federal financial assistance projects?

iii. How long might it take to implement the steps needed to increase or begin production of manufactured products that are compliant with the Manufactured Products NPRM's proposed requirements?

iv. If a plan is in place to manufacture products compliant with the Manufactured Products NPRM's proposed requirements, what is the volume of specific products that will be in compliance with these requirements and in what time frame?

v. Will the volume of manufactured products that are compliant with the Manufactured Products NPRM's proposed requirements be ramped up over time, and, if so, at what annual growth rate?

vi. What are the limiting factors for the product's ability to meet criteria for compliance under the Manufactured Products NPRM? For example, are there particular components of these products that cannot be mined, produced, or manufactured in the United States, and which make up a significant portion of the cost of the manufactured product? If so, please describe each component separately, and indicate approximately what percent of the total cost of all components of the manufactured products it represents.

2. Market Readiness

a. For each product you identified above, please provide your observations on the current and near-term domestic demand expected for these products or categories of products. Does this estimate of future demand take into account increases in Federal funding amounts for infrastructure under the BIL, enacted as the Infrastructure Investment and Jobs Act (Pub. L. 117–58) and the Inflation Reduction Act (Pub. L. 117–169)? Please explain.

b. Please provide information regarding whether the current and/or near-term domestic manufacturing capacity would be adequate to meet the expected market demand. Please specify any factors helping or preventing domestic manufacturing industry from meeting the expected demand today and in the near-term and provide information on the current and expected availability or unavailability of key components or sub-components of the product or category of products you specified.

c. Are there external factors affecting the supply of product that makes it difficult to credibly communicate the existence of increased demand, or to credibly commit that such demand will be forthcoming? If so, please describe those challenges as specifically as possible.

3. Timing

a. Where known, for each product or category of products for which you are providing information, please specify the current range of expected product delivery timeframes. Are any existing supply chain delays applicable or anticipated for the product or critical components of the product(s)?

b. Please provide information, if available, on expected delivery timeframe outlooks through the near-term future. Include information, if known, on whether current timing delivery concerns are related to any temporary disruption.

c. Provide information on the current and expected near-term average customer delivery time.

d. Provide information regarding global supply chain constraints, local permitting, safety requirements, and needs that may affect delivery timeframes or extend installation time.

4. Pricing

a. For each product identified above as being may be available only at higher prices than from foreign sources or from non-compliant domestic sources list the price differential in percentage terms between foreign and domestic sources of the product.

5. Other Considerations

a. If you answered ''No'' to Topic 1(a), are the quantities of the project typically used on FHWA-assisted projects small enough that they might fall below the thresholds specified in the De Minimis and Small Grants Waiver and thus be subject to that waiver?

b. Are there any other considerations that FHWA should take into account regarding production, products, product quality, or components of manufactured products used in FHWA-funded projects that are not covered by questions 1 through 3?

Shailen P. Bhatt,

Administrator, Federal Highway Administration.

[FR Doc. 2024–05181 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Revised Supplemental Environmental Assessment and Finding of No Significant Impact for the Proposed I–5 Rose Quarter Improvement Project

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (USDOT).

ACTION: Notice of availability.

SUMMARY: The FHWA is issuing this notice to advise other Federal, State, and local agencies, Tribes, and the public that a Revised Supplemental Environmental Assessment (RSEA) and Finding of No Significant Impact (FONSI) have been prepared in accordance with the National Environmental Policy Act for the proposed Interstate–5 (I–5) Rose Quarter Improvement Project to improve safety and operations on I–5 between Interstate–84 and Interstate–405 in the Rose Quarter District of downtown Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Keith Lynch, Division Administrator, Federal Highway Administration, 530 Center Street NE, Suite 420, Salem, OR 97301; *Telephone:* (503) 399–5740. Thomas Parker, Environmental Program Manager, Federal Highway Administration, 530 Center Street NE, Suite 420, Salem, OR 97301; *Telephone:* (503) 316–2549; *Email: thomas.w.parker@dot.gov.* Megan Channell, Rose Quarter Project Director, ODOT Region 1, 123 NW Flanders St., Portland, OR 97209; *Telephone:* 971–

233–6510; *Email: megan.channell@odot.oregon.gov.*

SUPPLEMENTARY INFORMATION: The FHWA and the Oregon Department of Transportation (ODOT) propose to undertake safety and operational improvements to I–5 through the Rose Quarter district in downtown Portland, Oregon. Federal cooperating agencies in the preparation of the RSEA and FONSI include the National Oceanic and Atmospheric Administration National Marine Fisheries Service, U.S. Army Corps of Engineers, and the U.S. Coast Guard.

The proposed improvements extend existing auxiliary lanes and adds a new auxiliary lane to improve safety and operations on I–5 between Interstate–84 and Interstate–405. Improvements also include a new highway cover to connect N Hancock Street to NE Hancock Street and provide buildable space, modifications to the Broadway-Weidler interchange, traffic flow revisions, and local system multimodal improvements. This RSEA evaluates the benefits and impacts of two alternatives: one in which the I–5 Project would move forward as planned (the Revised Build Alternative), and one in which the Project would not be built (the No-Build Alternative). The ODOT evaluated the Revised Build Alternative in the 2022 Supplemental Environmental Assessment (SEA) which was published on November 5, 2022, for a 50-day public comment period which ended on January 4, 2023. In response to public comments received on the SEA, ODOT refined the design of the Revised Build Alternative. This RSEA reflects changes to the SEA based on those design refinements.

Authority: 42 U.S.C. 4321 *et seq.;* 23 U.S.C. 139.

Keith Lynch,

FHWA Division Administrator, Salem, OR.

[FR Doc. 2024–05200 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0000]

Notice of Final Federal Agency Actions on Proposed I–5 Rose Quarter Improvement Project

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final. The actions relate to a proposed highway project, the Interstate-5 (I–5) Rose Quarter Improvement Project in the Rose Quarter District of downtown Portland, Oregon. Those actions grant approvals for the project.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency's actions on the highway project will be barred unless the claim is filed on or before August 9, 2024. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Keith Lynch, Division Administrator, Federal Highway Administration, 530 Center Street NE, Suite 420, Salem, OR 97301; *Telephone:* (503) 316–2540. Thomas Parker, Environmental Program Manager, Federal Highway Administration, 530 Center Street NE, Suite 420, Salem, OR 97301; *Telephone:* (503) 316–2549; *Email: thomas.w.parker@dot.gov.* Megan Channell, Rose Quarter Project Director, ODOT Region 1, 123 NW Flanders St., Portland, OR 97209; *Telephone:* 971–233–6510; *Email: megan.channell@odot.oregon.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing approvals for the following improvements project in the State of Oregon: the I–5 Rose Quarter Improvements Project. The actions by the agencies, and the laws under which such actions were taken, are described in the Revised Supplemental Environmental Assessment (RSEA) and Finding of No Significant Impact (FONSI) for the project, approved on March 6, 2024. The I–5 Rose Quarter Improvements Project RSEA, FONSI, and other project records are available by contacting FHWA or Oregon DOT at the addresses provided above. The RSEA and FONSI can be viewed and downloaded from the project website at *https://www.i5rosequarter.org* or obtained from any contact listed above. This notice applies to all Federal agency decisions that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671q].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303; 23 U.S.C. 138]; Landscaping and Scenic Enhancement [23 U.S.C. 319].

4. *Wildlife:* Endangered Species Act of 1973 [16 U.S.C. 1531–1544 and section 1536]; Marine Mammal Protection Act [16 U.S.C. 1361–1423h]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667d]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 306108]; Archeological Resources Protection Act of 1977 [54 U.S.C. 312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Section 404, section 401, and section 319 of the Clean Water Act [33 U.S.C. 1251–1387]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act, [16 U.S.C. 3901, 3921]; Wetlands Mitigation [23 U.S.C. 119(g) and 133(b)(14)]; Flood Disaster Protection Act [42 U.S.C. 4012a and 4106].

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Keith Lynch,

FHWA Division Administrator, Salem, OR.

[FR Doc. 2024–05198 Filed 3–11–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Electronic Filing of Form W–4

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning electronic filing of Form W–4.

DATES: Written comments should be received on or before May 13, 2024 to be assured of consideration

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include OMB control number 1545–1435 or Electronic Filing of Form W–4.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Electronic Filing of Form W–4.

OMB Number: 1545–1435.

Regulation Number: T.D. 8706.

Abstract: Information is required by the Internal Revenue Service to verify compliance with regulation section 31.3402(f)(2)–1(g)(1), which requires submission to the Service of certain withholding exemption certificates. The affected respondents are employers that choose to make electronic filing of Forms W–4 available to their employees.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not for-profit institutions, and Federal, State, local or Tribal governments.

Estimated Number of Respondents: 2,000.

Estimated Number of Responses: 160,000.

Estimated Time per Response: .25 hours.

Estimated Total Annual Burden Hours: 40,000 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 7, 2024.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2024–05208 Filed 3–11–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Open Meeting of the Financial Research Advisory Committee

AGENCY: Office of Financial Research, Department of the Treasury.

ACTION: Notice of open meeting.

SUMMARY: The Financial Research Advisory Committee for the Treasury's Office of Financial Research (OFR) is convening for its 22nd meeting on Thursday, March 28, 2024, in the Cash Room, Main Treasury, 1500 Pennsylvania Avenue NW, Washington, DC, beginning at 10:00 a.m. EST. The meeting will be open to the public and limited seating will be available.

DATES: The meeting will be held on Thursday, March 28, 2024, beginning at 10:00 a.m. EST.

ADDRESSES: The meeting will be held in the Cash Room, Main Treasury, 1500 Pennsylvania Ave. NW, Washington, DC. The meeting will be open to the public via live webcast at *https://usdotyorktel.rev.vbrick.com/#/events/db5886d0-5874-4f44-a344-d1672cb2f78a.* A limited number of seats will be available for those interested in attending the meeting in person, and those seats will be available on a first-come, first-served basis. Because the meeting will be held in a secured facility, members of the public who plan to attend the meeting MUST contact the OFR by email at *OFR_FRAC@ofr.treasury.gov* by 5 p.m. EST on Friday, March 22, 2024, to inform the OFR of their desire to attend the meeting in person and receive further instructions about building entry clearance.

Reasonable Accommodation: If you require a reasonable accommodation, please contact *ReasonableAccommodationRequests@treasury.gov.* Please submit requests at least five days before the event.

FOR FURTHER INFORMATION CONTACT: Patricia Driver, Designated Federal Officer, Office of Financial Research, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, at *OFR_FRAC@ofr.treasury.gov,* 202–213–4669.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided in accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 2, 10(a)(2), through implementing regulations at 41 CFR 102–3.150, *et seq.*

Public Comment: Members of the public wishing to comment on the business of the Financial Research Advisory Committee are invited to submit written statements by any of the following methods:

- *Electronic Statements.* Email the Committee's Designated Federal Officer at *OFR_FRAC@ofr.treasury.gov.*
- *Paper Statements.* Send paper statements in triplicate to the Financial Research Advisory Committee, Attn: Patricia Driver, Office of Financial Research, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220.

The OFR will post statements on the committee's website, *http://www.financialresearch.gov,* including any business or personal information provided, such as names, addresses, email addresses, or telephone numbers. The OFR will also make such statements available for public inspection and copying in the Department of the Treasury's library, Annex Room 1020, 1500 Pennsylvania Avenue NW, Washington, DC 20220 on official business days between the hours of 8:30 a.m. and 5:30 p.m. EST. You may make an appointment to inspect statements by telephoning (202) 622–0990. All statements, including attachments and other supporting materials, will be part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Tentative Agenda/Topics for Discussion: The committee provides an opportunity for researchers, industry leaders, and other qualified individuals to offer their advice and recommendations to the OFR, which, among other things, is responsible for collecting and standardizing data on financial institutions and their activities and for supporting the work of Financial Stability Oversight Council.

This is the 22nd meeting of the Financial Research Advisory Committee. Topics to be discussed include, financial stability concerns in commercial real estate, assessing risks and hedge fund activities, as well as private debt. For more information on the OFR and the committee, please visit the OFR website at *http://www.financialresearch.gov.*

Dated: March 6, 2024.

Emily Anderson,

Acting Deputy Director for Operations.

[FR Doc. 2024–05164 Filed 3–11–24; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Request for Information on the Department of Veterans Affairs

Peer Specialist Standard of Practice

AGENCY: Department of Veterans Affairs.

ACTION: Request for information.

SUMMARY: The Department of Veterans Affairs (VA) is requesting information to assist in developing a national standard of practice for VA Peer Specialists. VA seeks comments on various topics to help inform VA's development of this national standard of practice.

DATES: Comments must be received on or before May 13, 2024.

ADDRESSES: Comments must be submitted through *http://www.regulations.gov.* Except as provided below, comments received before the close of the comment period will be available at *http://www.regulations.gov* for public viewing, inspection, copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* VA will not post on *http://www.regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date will not be accepted.

FOR FURTHER INFORMATION CONTACT: Ethan Kalett, Office of Regulations, Appeals and Policy (10BRAP), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, 202–461–0500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

Authority

Chapters 73 and 74 of 38 U.S.C. and 38 U.S.C. 303 authorize the Secretary to regulate VA health care professions to make certain that VA's health care system provides safe and effective health care by qualified health care professionals to ensure the well-being of those veterans who have borne the battle.

On November 12, 2020, VA published an interim final rule confirming that VA health care professionals may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other State requirements that unduly interfere with their practice. 38 CFR 17.419; 85 FR 71838. Specifically, this rulemaking confirmed VA's current practice of allowing VA health care professionals to deliver health care services in a State other than the health care professional's state of licensure, registration, certification, or other State requirement, thereby enhancing beneficiaries' access to critical VA health care services. The rulemaking also confirmed VA's authority to establish national standards of practice for its health care professionals which would standardize a health care professional's practice in all VA medical facilities, regardless of conflicting State laws, rules, regulations, or other State requirements.

The rulemaking explained that a national standard of practice describes the tasks and duties that a VA health care professional practicing in the health care profession may perform and may be permitted to undertake. Having a national standard of practice means that individuals from the same VA health care profession may provide the same type of tasks and duties regardless of the State where they are located or the State license, registration, certification, or other State requirement they hold. We emphasized in the rulemaking and reiterate here that VA will determine, on an individual basis, that a health care professional has the proper education, training, and skills to perform the tasks and duties detailed in the national standard of practice, and that they will only be able to perform such tasks and duties after they have been incorporated into the individual's privileges, scope of practice, or functional statement. The rulemaking explicitly did not create any such national standards and directed that all national standards of practice would be subsequently created via policy.

Preemption of State Requirements

The national standard of practice will preempt any State laws, rules, regulations, or requirements that both are and are not listed in the national standard as conflicting, but that do in fact conflict with the tasks and duties as authorized in VA's national standard of practice. In the event that a State changes their requirements and places new limitations on the tasks and duties it allows in a manner that would be inconsistent with what is authorized under the national standard of practice, the national standard of practice will preempt such limitations and authorize the VA health care professional to continue to practice consistent with the tasks and duties outlined in the national standard of practice.

In cases where a VA health care professional's license, registration, certification, or other State requirement allows a practice that is not included in a national standard of practice, the individual may continue that practice so long as it is permissible by Federal law and VA policy, is not explicitly prohibited by the national standard of practice, and is approved by the VA medical facility.

Need for National Standards of Practice

It is critical that VA, the Nation's largest integrated health care system, develops national standards of practice to ensure, first, that beneficiaries receive the same high-quality care regardless of where they enter the system and, second, that VA health care professionals can efficiently meet the needs of beneficiaries when practicing within the scope of their VA employment. National standards are designed to increase beneficiaries' access to safe and effective health care, thereby improving health outcomes. The importance of this initiative has been underscored by the coronavirus disease 2019 (COVID–19) pandemic. The increased need for mobility in VA's workforce, including through VA's Disaster Emergency Medical Personnel System, highlighted the importance of creating uniform national standards of practice to better support VA health care professionals who practice across State lines. Creating national standards of practice also promotes interoperability of medical data between VA and the Department of Defense (DoD), providing a complete picture of a veteran's health information and improving VA's delivery of health care to the Nation's veterans. DoD has historically standardized practice for certain health care professionals, and VA has closely partnered with DoD to learn from their experience.

Process to Develop National Standards of Practice

As authorized by 38 CFR 17.419, VA is developing national standards of practice via policy. There will be one overarching national standard of practice directive that will generally describe Veterans Health Administration (VHA) policy; each individual national standard of practice will be an appendix to the directive. The directive and all appendices will be accessible on the VHA Publications website at *https://vaww.va.gov/vhapublications/* (internal) and *https://www.va.gov/vhapublications/* (external) once published.

To develop these national standards, VA is using a robust, interactive process that adheres to the requirements of Executive Order (E.O.) 13132 to preempt conflicting State laws, rules, regulations, or other requirements. The process includes consultation with internal and external stakeholders, including State licensing boards, VA employees, professional associations, Veterans Service Organizations, labor partners, and others. For each VA occupation, a workgroup comprised of VA health care professionals in the identified occupation conducts research to identify internal best practices that may not be authorized under every State license, certification, or registration, but would enhance the practice and efficiency of the profession throughout VA. If a best practice is identified that is not currently authorized by every State, the workgroup determines what education, training, and skills are required to perform such tasks and duties. The workgroup then drafts a proposed VA national standard of practice using the data gathered during the research and incorporates internal stakeholder feedback into the standard. The workgroup may consult with internal or external stakeholders at any point throughout the process.

The proposed national standard of practice is then internally reviewed, to include by an interdisciplinary VA workgroup consisting of representatives from Quality Management, VA medical facility Chief of Staff, Academic Affiliates, Veterans Integrated Services Network (VISN) Chief Nursing Officer, Ethics, Workforce Management and Consulting, Surgery, Credentialing and Privileging, VISN Chief Medical Officer, and Electronic Health Record Modernization.

Externally, VA hosts listening sessions for members of the public, professional associations, and VA employees to provide comments on the variance between State practice acts for a specific occupation and what should be included in the national standard of practice for that occupation. The Listening Session for Peer Specialists was held on September 21, 2023. No professional associations presented comments on the Peer Specialist scope of practice.

VA has developed a robust process to engage with partners, members of the public, States, and employees on the proposed national standard of practice. VA provides the proposed national standard of practice to our DoD partners as an opportunity to flag inconsistencies with DoD standards. VA also engages labor partners informally as part of a pre-decisional collaboration. Consistent with E.O. 13132, VA sends a letter to each State board and certifying organization or registration organization, as appropriate, which includes the proposed national standard and offers the recipient an opportunity to discuss the national standard with VA. After the State boards, certifying organizations, or registration organizations have received notification, the proposed national standard of practice is posted in the **Federal Register** for 60 days to obtain feedback from the public, professional associations, and any other interested parties. At the same time, the proposed national standard is posted to an internal VA site to obtain feedback from VA employees. Responses received through all vehicles—from State boards, professional associations, unions, VA employees, and any other individual or organization who provides comments via the **Federal Register**—will be reviewed. VA will make appropriate revisions in light of the comments, including those that present evidence-based practice and alternatives that help VA meet our mission and goals. VA will publish a collective response to all comments at *https://www.va.gov/standardsofpractice.*

After the national standard of practice is finalized, approved, and published in VHA policy, VA will implement the tasks and duties authorized by that national standard of practice. Any tasks or duties included in the national standard will be properly incorporated into individual health care professionals' privileges, scope of practice, or functional statement once it has been determined by their VA medical facility that the individual has the proper education, training, and skills to perform the task or duty. Implementation of the national standard of practice may be phased in across all VA medical facilities, with limited exemptions for health care professionals as needed.

Format for National Standard for Peer Specialists

The proposed format for national standards of practice when there are State certifications is as follows. The first paragraph provides general information about the profession and a broad list of tasks and duties these health care professionals can do. For this national standard, Peer Specialists are United States military veterans who self-identify with a lived experience of recovery from a mental health condition and have been professionally trained to help other veterans with similar experiences to identify and achieve specific life and recovery goals. This is an evolving profession both in and outside of VA. We reiterate that the proposed standard of practice does not contain an exhaustive list of every task and duty that each VA health care professional can perform. Rather, it is designed to highlight generally what tasks and duties the health care professionals perform and how this they will be able to practice within VA notwithstanding their State license, certification, registration, or other State requirements.

The second paragraph references the training and certification needed to practice this profession at VA. Qualification standards for employment of health care professionals by VA are outlined in VA Handbook 5005, Staffing, dated November 8, 2023. VA follows the requirements outlined in the VA qualification standards even if the requirements conflict with or otherwise differ from a State requirement. National standards of practice do not affect those requirements. This includes, but is not limited to, when a State requires a license to practice a specific occupation, but VA does not require a State license as part of the qualification standards. For Peer Specialists, VA qualification standards require an active, current, full, and unrestricted certification from a State or a not-for-profit entity with Peer Specialist training.

The third paragraph confirms that this profession can perform all the duties set by the State certification bodies. For Peer Specialists, VA reviewed State certification requirements and State-recognized non-profit organization certification requirements. VA found that 48 States certify Peer Specialists through a State certification or a non-profit entity and seven States do not regulate Peer Specialists. However, VA found no variance in how Peer Specialists practice in any State. VA thus proposes to adopt a national standard of practice for Peer Specialists that is consistent with what is permitted in all States. As previously noted, this VA national standard of practice is the first attempt at creating a comprehensive standard for Peer Specialists.

This national standard of practice does not address training because it will not authorize VA Peer Specialists to perform any tasks or duties not already authorized under their State certifications.

Following public and VA employee comments and revisions, each national standard of practice that is published into policy will also include the date for recertification of the standard of practice and a point of contact for questions or concerns.

Proposed National Standard of Practice for Peer Specialists

1. Peer Specialists are United States military Veterans who self-identify with a lived experience of recovery from a mental health condition and have been professionally trained to help other Veterans with similar experiences to identify and achieve specific life and recovery goals. Peer Specialist is an evolving profession both in and outside of VA, and a national scope of practice for this profession has not been previously developed or implemented. VA is the largest single employer of Peer Specialists in the United States. This VA national standard of practice is the first uniform set of guidelines to which Peer Specialists practice. Peer Specialists are actively engaged in their own recovery and wellness and provide individual and group-based peer support services to other veterans who use VA health care services. Peer Specialists share aspects of their personal recovery story and wellness strategies, when and where it is appropriate to do so, to be of help to others. They collaborate with other health care professionals on interdisciplinary treatment teams as the teams work toward shared goals to provide quality health care services for Veterans. Peer Specialists' tasks and duties include, but are not limited to:

a. Assisting Veterans to explore, identify, and make progress on their self-directed personal recovery and wellness goals.

b. Being role models and sharing elements of their personal experience, including their recovery stories, coping techniques, and self-help strategies to be of service to others.

c. Collaborating with Veterans and their treatment providers to identify and cultivate Veterans' skills and strengths that support their recovery goals.

d. Helping Veterans to learn new coping skills and self-help strategies to overcome fears and barriers that could inhibit the Veteran's personal recovery. This does not include facilitating psychotherapy protocols.

e. Advocating for Veterans when needed and supporting Veterans in learning to self-advocate for their own needs and interests.

f. Supporting Veterans in distress and collaborating with colleagues to connect Veterans with clinical providers' services and community services when needed.

g. Assisting Veterans to connect to available VA and community resources, including conducting outreach calls to educate and engage Veterans to connect with available VA services.

h. Facilitating peer support groups and co-facilitating with clinicians on other types of health and personal wellness groups. This does not include facilitating or co-facilitating psychotherapy groups.

i. Assisting Veterans with integration activities into their community, as consistent with Veterans' stated goals.

2. Peer Specialists in the Department of Veterans Affairs (VA) possess the training and peer specialist certification required by VA qualification standards. See VA Handbook 5005, Staffing Part II, Appendix F3, dated July 17, 2012.

3. VA Peer Specialists can, in collaboration with their supervisors, practice all duties covered by their peer specialist certification. VA reviewed certification requirements for this occupation in May 2023 and confirmed there is no variance in what is permitted by the state-issued peer specialist certifications. As of May 2023, the VA standard of practice is consistent with what is permitted in any state.

Request for Information

1. Are there any factors that would inhibit or delay the implementation of the aforementioned tasks and duties for VA health care professionals in any states?

2. Is VA's assessment of what tasks or duties States allow and do not allow accurate?

3. Are there any areas of variance between State certifications that VA should preempt that are not listed?

4. Is there anything else you would like to share with us about this VA national standard of practice?

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on February 13, 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.

[FR Doc. 2024–05237 Filed 3–11–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Tuesday,

No. 49 March 12, 2024

Part II

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for 12 Species on Hawai'i Island; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2023–0017; FXES1111090FEDR–245–FF09E21000]

RIN 1018–BG65

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for 12 Species on Hawai'i Island

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), designate critical habitat for 12 federally endangered species on the island of Hawai'i under the Endangered Species Act of 1973 (Act), as amended. In total, approximately 119,326 acres (48,289 hectares) on the island of Hawai'i, in the State of Hawaii, fall within the boundaries of the critical habitat designation. This rule extends the Act's protections to these species' designated critical habitats.

DATES: This rule is effective April 11, 2024.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov* under Docket No. FWS–R1–ES–2023–0017 and at *https://www.fws.gov/project/critical-habitat-hawaii-island-species*. Comments and materials we received are available for public inspection at *https://www.regulations.gov under* Docket No. FWS–R1–ES–2023–0017.

Availability of supporting materials: Supporting materials we used in preparing this rule, such as the draft recovery plan, 5-year status reviews, and other materials relating to this critical habitat designation, including coordinates or plot points or both from which the maps are generated, are available at *https://www.regulations.gov* under Docket No. FWS–R1–ES–2023–0017.

FOR FURTHER INFORMATION CONTACT: Earl Campbell, Project Leader, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard Room 3–122, Honolulu, HI 96850; telephone 808–792–9400. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act (16 U.S.C. 1531 *et seq.*), to the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species. Making a critical habitat determination can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. This rule designates approximately 119,326 *acres (ac) (*48,289 *hectares (ha)) as critical habitat for 12 federally endangered species (11 plants, 1 insect) on the island of Hawai'i in the State of Hawai'i.*

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

Previous Federal Actions

Please refer to the proposed and final listing rules (77 FR 63928, October 17, 2012; 78 FR 64638, October 29, 2013) and proposed critical habitat rule (88 FR 18756, March 29, 2023) for a detailed description of previous Federal actions concerning the species addressed in this final rule.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we solicited independent scientific review of the information contained in the proposed critical habitat rule (88 FR 18756, March 29, 2023). We sent the proposed rule to five independent peer reviewers and received three separate peer reviewer responses. The peer reviews can be found at *https://www.regulations.gov.* We incorporated the results of these reviews, as appropriate, into this final rule. A summary of the peer review comments and our responses can be found under Summary of Comments and Recommendations, below.

Summary of Changes From the Proposed Rule

After considering the comments we received during the public comment period on our March 29, 2023, proposed rule to designate critical habitat for the 12 federally endangered species on the island of Hawai'i (88 FR 18756) and relevant information that became available since the proposed rule published, we made changes to this final critical habitat rule. No changes were required for our economic analysis after considering public comments; thus, we finalized the economic analysis of the designation. We made many small, nonsubstantive changes and corrections throughout this document that do not affect the designation (*e.g.,* updating the Background discussion in this rule's preamble in response to comments, and making other minor clarifications). Below is a summary of changes made in this final rule; please note that an explanation of plant sections and their correlation to designated critical habitat units for the plants that are the subjects of this rule is provided under Final Critical Habitat Designation, below.

(1) We make minor clarifications and elaborate on our rationale for concluding in our proposed rule (88 FR 18756, March 29, 2023) that the designation of critical habitat is not prudent at this time for *Pritchardia lanigera* (loulu) and *Vetericaris chaceorum* (anchialine pool shrimp).

(2) We correct the range information for *Cyrtandra wagneri* to include only the Mauna Kea region, resulting in the removal of all unoccupied critical habitat units for this species. Specifically, this designation does not include critical habitat for *C. wagneri* that we proposed in units 23, 24 (Sections 8 and 9), 28, 29, 30, 42, 43, 44, 45, 46, and 51. The critical habitat we are designating for *C. wagneri* in this rule includes only two occupied units:

units 3 and 52 in Section 1. This is a decrease of approximately 72,469 ac (29,328 ha) from the critical habitat we proposed for *C. wagneri* on March 29, 2023 (88 FR 18756). However, because all of the unoccupied critical habitat units that we proposed for *C. wagneri* are also occupied by other plants for which we are designating critical habitat in this rule, not designating these units for *C. wagneri* does not change the total area designated as critical habitat in this rule.

(3) We remove the proposed *Drosophila digressa*—Unit 6 from this final designation; however, this same area was proposed, and remains in this final rule, as designated critical habitat for *Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae* in Section 6, units 16 and 40.

(4) We revise the critical habitat designation to add a new unit for *Drosophila digressa* (a new *Drosophila digressa*—Unit 6), based on new information we received in peer review comments regarding recent surveys in South Kona. Within the same boundaries of the new *Drosophila digressa*—Unit 6, we created a new plant Section 20 that contains Unit 56 for *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei.* The new unit (*Drosophila digressa*—Unit 6, and Unit 56 for *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei*) results in an increase of 224 ac (91 ha) of delineated critical habitat from the areas we proposed.

(5) Pursuant to section 4(b)(2) of the Act (16 U.S.C. 1533(b)), in this final designation, we exclude lands in 12 areas in 7 units owned by the following entities: the Kamehameha Schools; Parker Ranch Waipunalei, LLC; Parker Ranch Waiemi, LLC; State Department of Hawaiian Home Lands; Laupāhoehoe Nui; Kahua Ranch; and Queen Emma Foundation. This amounts to a decrease of approximately 3,172 ac (1,284 ha) from the critical habitat areas we proposed.

(6) We do not exclude The Nature Conservancy's land in Section 13 (Unit 41 for *Cyanea tritomantha, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae*) and *Drosophila digressa*—Unit 5 based on information we received from public comments. This area of approximately 986 ac (399 ha) is designated as critical habitat in this final rule.

(7) In the March 29, 2023, proposed rule (88 FR 18756), we erroneously included 125 ac (51 ha) as part of plant Section 8, Unit 24, even though those acres actually belonged in plant Section 8, Unit 44. We correct that error in this final rule by transferring in our acreage totals 125 ac (51 ha) from Unit 24 to Unit 44 in plant Section 8.

(8) In the March 29, 2023, proposed rule (88 FR 18756), we erroneously included 469 ac (190 ha) as part of plant Section 11, Unit 30, even though those acres actually belonged in plant Section 11, Unit 51. We correct that error in this final rule by transferring in our acreage totals 469 ac (190 ha) from Unit 30 to Unit 51 in plant Section 11.

(9) We made minor adjustments to the elevations we provided in the proposed rule related to the different ecosystem types which we used to determine the physical or biological features essential to each of the 12 species. We made these adjustments in this final rule to mirror exactly the elevations given in the scientific literature source from which each was derived. Specifically, we more accurately report: the elevation of the coastal ecosystem as less than 984 feet (ft) (300 meters (m)), instead of rounding to less than 980 ft; the elevation of the mesic forest as less than 6,562 ft (2,000 m), instead of rounding to less than 6,600 ft; the elevation of wet forest as less than 7,218 ft (2,200 m), instead of rounding to less than 7,300 ft; the elevation of mesic grassland and shrubland as 98 ft to 7,546 ft (30 to 2,300 m), instead of rounding to 100 ft to 7,500 ft; and the elevation of wet grassland and shrubland as 656 ft to 2,953 ft (200 to 900 m), instead of rounding to 660 ft to 2,950 ft.

(10) There are minor differences in area measurements reported in our March 29, 2023, proposed rule (88 FR 18756) compared to this final rule due to digital mapping discrepancies between Tax Map Key (TMK) parcel Geographic Information System (GIS) data (Hawaii Statewide GIS Program 2022, entire) and the National Oceanic and Atmospheric Administration's (NOAA's) Coastal Change Analysis Program coastline data (Office for Coastal Management 2023, entire). Additionally, we received updated TMK parcel GIS data from Hawaii County that resulted in a 23-ac (9-ha) discrepancy for Parker Ranch lands in this final rule when compared to the acreages presented in our March 29, 2023, proposed rule. As a result, we identified that we were considering for exclusion 349 ac (141 ha) of Parker Ranch land in Section 3, Unit 54, in the proposed rule, but that updated acreage which we exclude in the final rule is 372 ac (150 ha). Further, minor differences (1 to 2 acres or hectares) in areas reported between the proposed rule and this final rule may exist as an artifact of summing, rounding, and conversion from acreage to hectarage.

(11) We removed 4 ac (2 ha) from the proposed plant Section 2, Unit 53 and plant Section 8, Unit 44, in this final rule. These 4 ac (2 ha) consisted of small slivers, ranging in size from less than 0.01 ac (0 ha) to 1.09 ac (0.4 ha), that had been part of the proposed designation in Unit 53 and Unit 44. However, once we excluded the Kamehameha Schools land from Unit 53 and Unit 44 in the final designation, these slivers were left because the base layer and TMK layer did not align with each other after the removal of the Kamehameha Schools exclusion. This misalignment of the base layer and TMK layer is due to digital mapping discrepancies, and the slivered 4 ac (2 ha) left over as a result of this spatial analysis are artifacts of these discrepancies rather than real acres of land that are being included or excluded as part of the critical habitat designation.

Beyond those changes, this critical habitat designation is unchanged from what we proposed on March 29, 2023 (88 FR 18756).

Summary of Comments and Recommendations

In the proposed critical habitat rule published on March 29, 2023 (88 FR 18756), we requested that all interested parties submit written comments on the proposal by May 30, 2023. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. Digital newspaper notices inviting general public comment were published by Pacific Media Group, covering the communities of Maui and Hawai'i Island, as well as a radio and television broadcast airing on Hawai'i Public Radio and Hawai'i News Now, respectively. We held a public hearing on April 20, 2023. All substantive information we received during the comment period, as described above, on the proposal has either been incorporated directly into this final rule or is addressed below.

Peer Reviewer Comments

As noted above in Peer Review, we received comments from three peer reviewers on the proposed rule. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the species and their habitats. The peer reviewers generally concurred with our designations of critical habitat and conclusions, and provided additional information, clarifications, and

suggestions to improve the designation. The additional details and information received or raised by the peer reviewers have been incorporated into this final rule, as appropriate. Peer reviewer comments are addressed in the following summary.

(1) Comment: One reviewer provided information regarding habitat conditions that do not support *Drosophila digressa* in Kīpāhoehoe Natural Area Reserve in *Drosophila digressa*—Unit 6.

Our response: The Kīpāhoehoe Natural Area Reserve was not occupied by *Drosophila digressa* at the time of listing. Based on the information available at the time of our proposed critical habitat designation, this area appeared to contain the physical or biological features essential to the conservation of the species, and we therefore included it in our proposed designation. The commenter provided information on the habitat conditions of Kīpāhoehoe Natural Area Reserve in *Drosophila digressa*—Unit 6 that were not available to us at the time we proposed critical habitat. After we reviewed the new information provided by the commenter, we agree that the wet to mesic forest there does not support the host plants for *D. digressa,* and that the younger lava flows outside of the kīpuka (vegetated areas surrounded by bare lava flows) are unsuitable for the host plants of *D. digressa.* Because the new information indicates that the area likely does not contain the host plants for *D. digressa,* and is therefore unsuitable for *D. digressa,* we removed the proposed *Drosophila digressa*—Unit 6 from this final critical habitat designation.

(2) Comment: One reviewer suggested that additional critical habitat should be designated for a new population of *Drosophila digressa* discovered in 2022 in lower Honomalino Forest Reserve within existing plant critical habitat unit Hawaii 17—*Asplenium dielerectum*—a and Hawaii 17—*Flueggea neowawraea*—a (see 50 CFR 17.99(k) and 68 FR 39624 at 39740–39741, July 2, 2003).

Our response: In our March 29, 2023, proposed critical habitat rule (88 FR 18756), we requested from the public any new information regarding additional areas occurring within the range of each species that should be included in our critical habitat designation because they were occupied at the time of listing and contain the physical or biological features essential to the conservation of the species. The commenter provided new information on a population of *Drosophila digressa* that was unknown to the Service at the time we delineated the proposed critical habitat designation (Magnacca 2023a, pers. comm.; Magnacca 2023b, pers. comm.). We expect that this *D. digressa* population was present at the time the species was listed because the location of this population contains suitable habitat for *D. digressa,* is protected as State Forest Reserve land, and is within the known range of the species. However, because this area was previously unsurveyed, the population was not discovered until surveyed in 2022. We considered the commenter's suggestion to add the new population of *D. digressa* to the area currently designated as plant critical habitat unit Hawaii 17—*Asplenium dielerectum*—a and Hawaii 17—*Flueggea neowawraea*—a (see 50 CFR 17.99(k)), but we determined that the newly discovered *D. digressa* population does not overlap with that existing critical habitat. However, after reviewing the information on the new population provided by the commenter and applying our critical habitat delineation methodology (as described under Criteria Used To Identify Critical Habitat in our March 29, 2023, proposed critical habitat rule (88 FR 18756 at 18765–18767)), we determined that the new *D. digressa* population area meets the criteria for designation as critical habitat. Therefore, in this rule, we designate a new critical habitat unit in South Kona named *Drosophila digressa*—Unit 6, as described above in Summary of Changes from the Proposed Rule and detailed below. (Note that this new *Drosophila digressa*—Unit 6 replaces the proposed *Drosophila digressa*—Unit 6, which we discuss above in our response to *(1) Comment.*)

Additionally, we applied our critical habitat delineation methodology to the new *Drosophila digressa*—Unit 6 in South Kona and found that it also meets the criteria for two plant species included in this rule, *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei.* Using the same boundaries of the *Drosophila digressa*—Unit 6, we created a new plant Section 20, which contains Unit 56 for *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei.* The new unit (*Drosophila digressa*—Unit 6, and Unit 56 for *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei*) is 224 ac (91 ha) and consists of State-owned lands.

(3) Comment: One reviewer provided additional information and commented that *Cyrtandra wagneri* should be added to Unit 54 because the species was found in the Kohala Mountains as of 2009.

Our response: The reviewer did not provide specific information on the current status of *Cyrtandra wagneri* in Unit 54, except for photos of the observed plant. We asked a State of Hawaii botanist to review the photographs provided by the reviewer, and they noticed a slight difference in the flower structure of the photographed plant from that of *C. wagneri,* which they thought suggested that the plant in the photograph was most likely a hybrid or another species of *Cyrtandra.* We reviewed the best available information describing the occurrences and physical or biological features essential to the conservation of *C. wagneri* in this unit and found no records in our database indicating that *C. wagneri* occurred in the Kohala Mountains. Our species range map for *C. wagneri* does not include the Kohala Mountains; therefore, this occurrence is outside the known range of *C. wagneri.* In Laupāhoehoe, where *C. wagneri* naturally occurs, *C. wagneri* has been documented to hybridize with the endangered *Cyrtandra tintinnabula.* The Service and the State no longer have access to survey this area, and, at this time, the best available information indicates that *C. wagneri* has become hybridized or been extirpated from Unit 54. Therefore, we do not designate Unit 54 as critical habitat for *C. wagneri* in this rule.

Federal Agency Comments

(4) Comment: The U.S. Army at Pōhakuloa Training Area (PTA) provided comments specific to the proposed critical habitat designation for *Schiedea hawaiiensis* in the Pu'u Anahulu region adjacent to the PTA (Unit 55). The Department of Defense (DoD) awarded Readiness and Environmental Protection Integration (REPI) Program grants to the State of Hawaii Division of Forestry and Wildlife (DOFAW) to implement conservation actions at Pu'u Anahulu, creating a Federal nexus for activities at Pu'u Anahulu that are implemented under REPI, requiring consultation under section 7(a)(2) of the Act. As a result, the commenter stated that these activities will likely increase their consultation workload. They also stated that because wildfire risk to the proposed critical habitat unit in Pu'u Anahulu is greater than that to *Schiedea hawaiiensis* and its habitat at the PTA installation, they would need to implement additional conservation measures to minimize wildfire risk to the proposed critical habitat unit as a result of military training at PTA. They also expressed concern that training restrictions may increase in comparison to those currently implemented or anticipated as part of the planned comprehensive programmatic

consultation for PTA. They stated that the additional economic and administrative burden (*e.g.,* section 7 consultation) to the U.S. Army that would result from the proposed critical habitat at Pu‘u Anahulu was not accounted for in the draft economic analysis.

Our response: The Pu‘u Anahulu area that the commenter refers to is a State of Hawaii Game Management Area within critical habitat Unit 55. As such, the critical habitat designation there will affect the DoD only for activities that they fund at Pu‘u Anahulu through the REPI Program. Activities funded through the REPI Program would include wildland fire risk management conducted by the State of Hawaii that would provide a conservation benefit to *Schiedea hawaiiensis.* Due to the nature of these management actions, we anticipate any additional consultation burdens resulting from the Service's designation of Unit 55 as critical habitat would be primarily administrative. Further, our understanding is that the DoD is already conducting and planning conservation measures to minimize wildfire risk as a result of military training at PTA both on and off of the installation, and that these measures would be no different than those that may apply to the new critical habitat in Unit 55. We will continue to work with the DoD's REPI Program to assist them in meeting their section 7 consultation requirements. Further, any additional future conservation measures to minimize wildfire risk to Unit 55 as a result of military training at the adjacent PTA will depend upon the U.S. Army's proposed action as described in their upcoming biological assessment.

State Agency Comments

(5) Comment: The State of Hawaii DOFAW questioned why the lands of Pu‘u Anahulu in Unit 55 are being designated, as these lands constitute a Game Management Area and have a draft habitat conservation plan that covers management of the area. Additionally, the State mentioned that DoD's REPI Program is funding fencing, fuels management, and seed collection/banking for all known rare species in the area and is concerned that additional compliance measures may be required if critical habitat is designated.

Our response: As described in our March 29, 2023, proposed rule, we delineated critical habitat areas based on the defined methodology and identified areas that contain the physical or biological features essential to the conservation of the species. While Section 19, Unit 55 is within a Game Management Area, the area contains the physical or biological features essential to the conservation of *Schiedea hawaiiensis.* The characteristics of Section 19 are described under *Descriptions of Critical Habitat,* below. Additionally, existing conservation actions being led by DOFAW that occur within Section 19 contribute to the conservation of *S. hawaiiensis* habitat despite the area's categorization as a Game Management Area.

The most recent draft habitat conservation plan (HCP) for game management at Pu‘u Wa‘awa‘a and Pu‘u Anahulu was published on August 14, 2017, as a ''working document.'' The DOFAW last received funding under section 6 of the Act from the Service's habitat conservation planning assistance program in 2011 to complete the final HCP, which was not completed (Hawaii Department of Land and Natural Resources (DLNR)–DOFAW 2017, entire). We met with DOFAW during the March 29, 2023, proposed rule's (88 FR 18756) comment period to discuss planned actions for the Pu‘u Anahulu area, and they indicated that planned actions would support the habitat for *Schiedea hawaiiensis* and other native at-risk species. However, apart from these planned actions, we confirmed with DOFAW that development of the draft game management HCP was discontinued. According to DOFAW and our records, there is currently no support to continue developing the draft HCP or game management plan. In regard to REPI, we acknowledge the importance of the conservation actions that will benefit rare species and their habitats resulting from the DoD's REPI Program funding to DOFAW for conservation actions in the Pu‘u Anahulu area. As such, we are working with DoD's REPI Program to assist them in meeting their section 7 consultation requirements, independent of the potential HCP.

The Service is not relieved of its statutory obligation to designate critical habitat based on the contention that such designation will not provide additional conservation benefit or because adequate protections are already in place (see Special Management Considerations or Protection, below). If any area provides the physical or biological features essential to the conservation of the species, even if that area is already well managed or protected, that area still qualifies as critical habitat under the statutory definition.

(6) Comment: The State of Hawaii DOFAW stated that plant Section 18 (Unit 50 for *Cyrtandra nanawaleensis,* in the Halepua‘a Section of the Nānāwale Forest Reserve) is severely degraded and unlikely to support any more remnant *Cyrtandra nanawaleensis.* They stated that the most recent monitoring of that location indicated that very few plants remain, despite protections from pigs.

Our response: When the October 29, 2013, final listing rule for *Cyrtandra nanawaleensis* was published (78 FR 64638), the Halepua‘a section of the Nānāwale Forest Reserve was one of five known occurrences for this species. As directed by the Act, we proposed as critical habitat those areas occupied by the species at the time of listing that contain the physical or biological features essential to the conservation of the species and which may require special management considerations or protection. At this time, the best available information indicates that *C. nanawaleensis* occupied plant Section 18 (Unit 50 for *Cyrtandra nanawaleensis*) at the time of listing. In addition, the best available information, which includes the most recent 5-year review for *C. nanawaleensis* (Service 2020, pp. 9–10), indicates that plant Section 18 is still occupied and contains the physical or biological features essential to the conservation of the species. Therefore, we are designating Unit 50 as critical habitat for *Cyrtandra nanawaleensis* in this rule.

(7) Comment: The State of Hawaii DOFAW stated that they are not aware of *Schiedea hawaiiensis* occurring on State-owned lands in plant Section 19 (Unit 55). They questioned why critical habitat is being designated on State lands in this parcel, but not on Federal lands where *Schiedea hawaiiensis* is known to occur. They claim that the DoD has more protected lands with the species' suitable habitat type than exist on the adjacent State land, and that DoD activities pose one of the greatest threats—fire—as demonstrated by August 2022's boundary-crossing Leilani fire.

Our response: We agree that there are no known occurrences of *Schiedea hawaiiensis* on State-owned lands in Section 19 (Unit 55). We identified Section 19 (Unit 55) as unoccupied critical habitat for *S. hawaiiensis.* Unoccupied areas are needed for the expansion or augmentation of reduced populations or the reestablishment of populations. The Act specifically requires the Service to designate critical habitat for listed species to the maximum extent prudent and determinable and does not restrict such designation to particular land ownership. Rather, areas that meet the definition of critical habitat, as determined on the basis of the best scientific data available, are proposed

for designation. We are designating critical habitat for *S. hawaiiensis* only on State-owned lands in Section 19 (Unit 55) because the Federal lands (*i.e.,* the Pōhakuloa Training Area) where *S. hawaiiensis* occurs are exempt from the critical habitat designation in accordance with section 4(a)(3)(B)(i) of the Act (see Exemptions, below).

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any areas owned or controlled by the DoD that are subject to an integrated natural resources management plan (INRMP), if the Secretary determines that such a plan provides a benefit to the species for which critical habitat is proposed for designation. An INRMP integrates the military mission of the installation with stewardship of the natural resources found there and must provide benefits to wildlife and their habitats. The DoD's current INRMP at Pōhakuloa Training Area (PTA) in plant Section 19 provides protection and enhancement of *S. hawaiiensis* and its habitat through management actions including, but not limited to, seed collection and storage, propagation and planting of cultivated plants, and ungulate fencing for protection of wild populations. We have determined that this INRMP provides conservation benefits to *S. hawaiiensis;* as such, the PTA lands are exempt from critical habitat designation in accordance with section 4(a)(3)(B)(i) of the Act. While we acknowledge the State lands adjacent to the PTA may be valuable to the conservation of *S. hawaiiensis* and other wildlife, the Act does not provide for exemptions outside of DoD lands (see Exemptions, below). Although State lands may qualify for exclusion under certain circumstances (see Consideration of Impacts under Section 4(b)(2) of the Act, below), we found no reason to identify the State lands adjacent to PTA as lands we were considering for exclusion in our March 29, 2023, proposed rule, nor did we receive a request for their exclusion after publication of the proposed rule.

(10) Comment: The State of Hawaii DOFAW stated that critical habitat plant Sections 4, 5, 6, 7, 8, 9, 11, 12, and 13 are not appropriate for the recovery of *Schiedea diffusa* ssp. *macraei, Cyrtandra wagneri,* and/or *Stenogyne cranwelliae,* because they are outside of the species' historical ranges.

Our response: While the State of Hawaii may use a different method to define historical ranges, we do not agree that the critical habitat units we are designating are outside of the historical ranges of the species to which the commenter referred. We used U.S. Geological Survey (USGS) species' range maps (Price et al. 2012, unpaginated), which include not only sites of known occupancy, but also geospatially projected habitat likely to have been occupied by the species historically based on climatic and vegetation data. We applied the critical habitat delineation methodology (as described under Criteria Used To Identify Critical Habitat in our March 29, 2023, proposed critical habitat rule (88 FR 18756 at 18765–18767)) to each of the plant sections identified in the State's comment.

As a result of this analysis, the Service is retaining in this designation the areas noted by the commenter. The Service's range maps for *Schiedea diffusa* ssp. *macraei* and *Stenogyne cranwelliae* overlap with these plant sections, and factors used to delineate the critical habitat boundaries for these species are consistent with our critical habitat methodology. These factors include information on known past and present locations of the species, landcover and ecosystem data sources by USGS Carbon Assessment Landcover Data (Selmants et al. 2017, entire), recovery areas described by the species' draft recovery plan, projections of geographic ranges of Hawaiian plant species (Price et al. 2012, entire; Service 2022b–l, entire), and adequacy of habitat to allow for the larger populations needed to meet recovery goals (as described in the draft recovery plan (Service 2022a, entire)). We considered all of these factors to delineate the critical habitat boundaries for these species, and these areas are essential for the conservation of these species. As a result, in this final rule, we retain the designations of critical habitat for *Schiedea diffusa* ssp. *macraei* and *Stenogyne cranwelliae* in plant Sections 4, 5, 6, 8, 9, 11, 12, and 13 as proposed.

For information about plant Section 7, and our final critical habitat designation for *Cyrtandra wagneri,* see Summary of Changes from the Proposed Rule, above, and Final Critical Habitat Designation, below.

(11) Comment: The State of Hawaii DOFAW recommended that *Schiedea diffusa* ssp. *macraei* not be removed from plant Section 3. The DOFAW stated that although the *Schiedea diffusa* from Kohala is actually the subspecies *diffusa* (confirmed by experts on the genera), and not *Schiedea diffusa* ssp. *macraei,* this has not been formally recognized.

Our response: We agree that critical habitat for *Schiedea diffusa* ssp. *macraei* should be designated in Section 3 (Units 8, 9, and 54). The additional information provided is reliable and the best available information; therefore, we include the information provided by the commenter in this final critical habitat designation. No change is necessary to Section 3 (Units 8, 9, and 54), as the relevant units are designated as critical habitat for *Schiedea diffusa* ssp. *macraei* in this final rule.

(12) Comment: The State of Hawaii commented that although *Schiedea diffusa* ssp. *macraei* is not known from the geographic area of plant Section 1 (Units 3 and 52), it is an area that supports high-quality habitat that hosts a similar suite of species found near the historical location for *Schiedea diffusa* ssp. *macraei* and could be a potential introduction site.

Our response: In our March 29, 2023, proposed rule, we proposed plant Section 1 (Units 3 and 52) as critical habitat for *Schiedea diffusa* ssp. *macraei* along with several other plants. The type collection by Macrae in 1825 of *Schiedea diffusa* ssp. *macraei* appears to have come from the slopes of Mauna Kea; however, no individuals have been collected from Mauna Kea in recent times (Wagner et al. 2005a, p. 106). We included the information provided by the commenter in this final rule. No change is necessary to Section 1 (Units 3 and 52), as the relevant units are designated as critical habitat for *Schiedea diffusa* ssp. *macraei* in this final rule.

(13) Comment: The State of Hawaii DOFAW commented that they support designating critical habitat but stated that the process could be improved by incorporating a slightly more detailed assessment of habitat quality, potential for habitat protection and ecosystem restoration, suitability as remnant habitat, and potential as reintroduction areas, as well as species' history and distribution. In addition, they state that targeted outreach to private landowners and increased collaboration could be beneficial.

Our response: As described in the March 29, 2023, proposed rule, within areas where we have information regarding species' observation and distribution, annual precipitation, elevation, soil, substrate, associated native plant genera, landcover and ecosystem data, and projections of species' geographic ranges, we included that information in our analysis. We considered the best available information and the physical or biological features essential to the conservation of each species in the critical habitat designation. We met with private landowners to help explain this critical habitat designation. We provided information about our compilation of available information on

species and habitat areas on Hawai'i Island, and requested updated information from landowners. We reviewed and incorporated new information from these meetings into this final rule. We acknowledge that the State has been a strong collaborator in developing our critical habitat areas, and we look forward to continued engagement.

Public Comments

(14) Comment: One commenter requested clarification on the exclusion policy and further justification for not including exempted areas.

Our response: Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that critical habitat is exempted on areas owned or controlled by the DoD that are subject to an integrated natural resources management plan prepared under 16 U.S.C. 670a that provides benefit to the listed species under consideration for critical habitat designation. In addition, an area may be excluded from critical habitat under section 4(b)(2) of the Act based on economic impacts, impacts on national security, or any other relevant impacts, if the benefits of the exclusion outweigh the benefits of inclusion as critical habitat and the failure to designate the area as critical habitat will not result in the extinction of the species (see 50 CFR 424.19 and 81 FR 7226, February 11, 2016). Details about exemptions and exclusions, and justification for those relevant to this critical habitat designation, can be found below under Exemptions and Consideration of Impacts under Section 4(b)(2) of the Act.

(15) Comment: One commenter stated that the greatest risk and current threat to the palm (*Pritchardia lanigera*) are rats that consume seeds, thereby hindering palm reproduction, and that collection is not a threat to the palm.

Our response: Pritchardia lanigera is easy to identify and may be attractive to collectors of rare palms for personal use, for trade, or for sale (Shirey et al. 2013, pp. 301–302). Several nurseries advertise and sell *Pritchardia* palms, including *P. lanigera* and other federally listed *Pritchardia* species, indicating that *Pritchardia* are attractive to some collectors. Collection is a threat to *P. lanigera* that would likely increase if we were to designate critical habitat for the species, as such designation would aid collectors in locating occurrences of the species (Shirey et al. 2013, p. 307; Weisenberger 2023, pers. comm.). Therefore, the designation of critical habitat for *Pritchardia lanigera* is not prudent due to the threat of collection.

(16) Comment: One commenter disagreed with the not-prudent critical habitat determination for *Vetericaris chaceorum.* When the Service listed *V. chaceorum* as endangered, overcollection for commercial and recreational purposes was not listed as a threat to the species. The commenter stated that *V. chaceorum* has only been documented in two specific locations, which have already been identified in the species' listing, have already been disclosed in the **Federal Register**, and are found easily online.

Our response: Vetericaris chaceorum is one of several different species and taxon of Hawaiian anchialine pool shrimp and is the largest of the anchialine pool shrimp found in Hawai'i (Yamamoto et al. 2015, p. 40). Anchialine pools are sensitive discrete ecosystems, and a single pool system can be home to many different species of anchialine pool shrimp.

We agree with the commenter that we did not cite overcollection as a threat to *V. chaceorum* when we listed it as endangered (78 FR 64638; October 29, 2013, pp. 63978–63978). However, after listing *V. chaceorum,* new information has become available highlighting a new threat in the form of collection and overutilization, as described in our proposed rule (88 FR 18756, March 29, 2023). Coincidentally after listing *V. chaceorum,* popularity in the aquarium trade of another Hawaiian anchialine shrimp species, *Halocaridina rubra,* commonly called the Hawaiian red shrimp or volcano shrimp, has increased worldwide (Yamamoto et al. 2015, p. 83). This increase in collection activities of *H. rubra* has resulted in a risk to *V. chaceorum,* due to these two species sharing a similar appearance and habitat preferences. The shrimp that are being harvested are primarily *H. rubra,* which is not endangered, but as the popularity of this business increases there is risk that the endangered *V. chaceorum* may either intentionally or accidentally be harvested and become part of the aquarium trade. Collectors may target *V. chaceorum* due to its similar appearance, rarity, and aesthetic, or collectors attempting to harvest the *H. rubra* that occur in the same pools as *V. chaceorum* may accidentally harvest both species (Sakihara 2012, entire). Because this shrimp is so rare, a single person with a hand-net could do irreparable damage to a population of *V. chaceorum* (Yamamoto 2015, pers. comm.).

Although more than 400 of the estimated 520 to 560 anchialine pool habitats have been surveyed on the island of Hawai'i, *V. chaceorum* has only been documented from two locations, indicating that this species has a very limited range, likely due to its behavior and salinity preferences (see 78 FR 64638, October 29, 2013). While general occurrence locations were included in the October 29, 2013, rule listing *V. chaceorum* as an endangered species, specifically defining occupied areas by geographic coordinates through a critical habitat designation may pose a risk to *V. chaceorum* by causing increased unauthorized collection by individuals seeking *Halocaridina rubra,* a prey source for *V. chaceorum.*

(17) Comment: The Nature Conservancy stated the Service should have designated as critical habitat areas occupied by *Drosophila digressa* in mesic forest below Kona Hema Preserve at Honomalino, and at Kīpuka Punahou.

Our response: We have reviewed the new information provided by the commenter, as well as similar information provided by a peer reviewer, regarding *Drosophila digressa* occurrences, and we evaluated the areas for inclusion in this critical habitat designation. The Nature Conservancy's suggestion regarding Honomalino is supported by information provided by one peer reviewer, as described above in Summary of Changes from the Proposed Rule. We have determined that the Honomalino area the commenter suggested for inclusion should be included in this critical habitat designation, and we include it in this designation as a new *Drosophila digressa*—Unit 6. The area is occupied by *D. digressa* as a new population discovered in 2022, has at least one physical or biological feature essential to the conservation of *D. digressa,* and may require special management considerations or protection.

We do not, however, include Kīpuka Punahou, which is also known as Kīpuka 9 located along Saddle Road, in this designation. The commenter did not provide any information to indicate that this area is currently occupied by *Drosophila digressa,* and the best available information indicates that the species was last observed in this area in 1986 (Hawaii Natural Heritage Program 2011, in litt.). Further, because of the lack of breeding substrate in the area, an individual *Drosophila digressa* observed in Kīpuka Punahou would likely be a vagrant (Magnacca 2012, pers. comm., entire).

Background

For species with Hawaiian common names, we prefer to, and will, include Hawaiian language spellings, including diacritical marks, to the degree possible and appropriate in the preambles of our **Federal Register** documents. For the

text to be codified in the Code of Federal Regulations (CFR), however, we will omit diacritical marks to ensure that no errors are inadvertently incorporated during the codification process.

Species Descriptions

We provide a brief description for each of the 14 species addressed in this rule, below.

Bidens hillebrandiana ssp. *hillebrandiana* (koʻokoʻolau), a short-lived perennial herb in the sunflower family (Asteraceae), occurs only on the island of Hawaiʻi (Ganders and Nagata 1999, pp. 275–276). Historically, *B. hillebrandiana* ssp. *hillebrandiana* was known from two locations along the windward Kohala coastline, in the coastal and dry cliff ecosystems, often along rocks just above the ocean (Degener and Wiebke 1926, in litt.; Flynn 1988, in litt.).

Cyanea marksii (hāhā), a short-lived perennial palmlike shrub in the bellflower family (Campanulaceae), is found only on the island of Hawaiʻi. Historically, *C. marksii* was known from the Kona district, in the lowland wet and montane wet ecosystems (Lammers 1999, p. 457; Hawaiʻi Biodiversity Mapping Program (HBMP) database 2010b).xxxxxxx

Cyanea tritomantha (ʻakū), a short-lived perennial palmlike shrub in the bellflower family (Campanulaceae), is known only from the island of Hawaiʻi (Pratt and Abbott 1997, p. 13; Lammers 2004, p. 89). Historically, this species was known from the windward slopes of Mauna Kea, Mauna Loa, Kīlauea, and the Kohala Mountains, in the lowland wet, montane wet, and wet cliff ecosystems (Pratt and Abbott 1997, p. 13).

Cyrtandra nanawaleensis (haʻiwale), a short-lived perennial shrub or small tree in the African violet family (Gesneriaceae), is known only from the island of Hawaiʻi (Wagner and Herbst 2003, p. 29; Wagner et al. 2005b). Historically, *C. nanawaleensis* was known only from the lowland wet ecosystems in the Puna district (St. John 1987, p. 500; Wagner et al. 1988, in litt.; HBMP 2010d).

Cyrtandra wagneri (haʻiwale), a short-lived perennial shrub or small tree in the African violet family (Gesneriaceae), occurs only on the island of Hawaiʻi (Lorence and Perlman 2007, p. 357). Historically, *C. wagneri* was known in the lowland wet ecosystem along the northeast side of the island (Lorence and Perlman 2007, p. 359).

Melicope remyi (no common name), a long-lived perennial shrub or shrubby tree in the rue family (Rutaceae), occurs only on the island of Hawaiʻi (Stone et al. 1999, p. 1210; Service 2010, pp. A–11, 4–74). Historically, *M. remyi* was known from a few scattered individuals on the windward slopes of the Kohala Mountains and several small populations on the windward slopes of Mauna Kea, in the lowland wet and montane wet ecosystems (Stone et al. 1999, p. 1210; HBMP 2010f).

Phyllostegia floribunda (no common name), a short-lived perennial subshrub in the mint family (Lamiaceae), is found only on the island of Hawaiʻi (Wagner 1999, p. 268; Wagner et al. 1999a, p. 815). Historically, *P. floribunda* was reported in the lowland wet, montane mesic, and montane wet ecosystems at scattered sites along the eastern side of the island.

Pittosporum hawaiiense (hōʻawa, hāʻawa), a small, long-lived perennial tree in the pittosporum family (Pittosporaceae), is known only from the island of Hawai'i (Wagner et al. 1999b, p. 1,044). Historically, *P. hawaiiense* was known from the leeward side of the island, from the Kohala Mountains south to Kaʻū, in the lowland mesic, montane mesic, and montane wet ecosystems (Wagner et al. 1999b, p. 1,044).

Pritchardia lanigera (loulu), a medium-sized, long-lived perennial tree in the palm family (Arecaceae), is found only on the island of Hawaiʻi (Read and Hodel 1999, p. 1,371; Hodel 2007, pp. 10, 24–25). Historically, *P. lanigera* was known from the Kohala Mountains, Haāmākua district, windward slopes of Mauna Kea, and southern slopes of Mauna Loa, in the lowland mesic, lowland wet, montane wet, and wet cliff ecosystems (Read and Hodel 1999, p. 1,371; National Park Service 2015, pp. 467–468)

Schiedea diffusa ssp. macraei (no common name), a short-lived perennial climbing herb in the pink family (Caryophyllaceae), is reported only from the island of Hawaiʻi (Wagner et al. 2005c; Wagner et al. 2005a, p. 106). Historically, *S. diffusa* ssp. *macraei* was known from the Kohala Mountains, the windward slopes of Mauna Loa, and the Olaʻa Tract of Hawaiʻi Volcanoes National Park, in the montane wet ecosystem (Perlman et al. 2001, in litt.; Wagner et al. 2005a, p. 106; HBMP 2010g).

Schiedea hawaiiensis (māʻoliʻoli), a short-lived perennial herb in the pink family (Caryophyllaceae), is known only from the island of Hawaiʻi (Wagner et al. 2005a, pp. 92–96). Historically, *S. hawaiiensis* was known from a single site between Mauna Loa and Mauna Kea mountains in the montane dry ecosystem (Hillebrand 1888, p. 33; Wagner et al. 2005a, pp. 92–96).

Stenogyne cranwelliae (no common name), a short-lived perennial vine in the mint family (Lamiaceae), is known only from the island of Hawaiʻi. Historically, *S. cranwelliae* was known from the Kohala Mountains, in the montane wet and wet cliff ecosystems (Weller and Sakai 1999, p. 837).

Drosophila digressa (Hawaiian picture-wing fly), a member of the family Drosophilidae, is found only on the island of Hawaiʻi and historically known from five locations on the island in elevations ranging from approximately 2,000 to 4,500 feet (ft) (610 to 1,370 meters (m)), in the lowland mesic, montane mesic, and montane wet ecosystems (Hardy and Kaneshiro 1968, p. 182; Montgomery 1975, p. 95; Magnacca 2012, pers. comm.). This species is small, with adults ranging in size from 0.15 to 0.19 inches (in) (4.0 to 5.0 millimeters (mm)) in length. Adults are brownish yellow in color and have yellow-colored legs and hyaline (shiny-clear) wings with prominent brown spots. Like many endemic Hawaiian Drosophilidae species, *D. digressa* are highly host-plant-specific (Magnacca et al. 2008, p. 1), relying on the decaying stems of *Charpentiera* spp., *Ceodes brunoniana* (previously known as *Pisonia brunoniana*), and *Rockia sandwicensis* (previously known as *Pisonia sandwicensis*) for reproduction and larval substrate (Magnacca et al. 2008, pp. 11, 13; Magnacca 2012, pers. comm.).

Vetericaris chaceorum (anchialine pool shrimp), a small shrimp in the family Procarididae, is endemic to Hawaiʻi. Anchialine pools are coastal, land-locked bodies of water that have underground hydrological connections to the ocean, contain varying levels of salinity, and show tidal fluctuations in water level. Vetericaris chaceorum is one of seven described species of hypogeal (underground) shrimp found in the Hawaiian Islands that occur in anchialine pools (Brock 2004, p. 6) and is relatively large in size for a hypogeal shrimp species; adult *V. chaceorum* measure approximately 2.0 in (5.0 centimeters (cm)) in total body length, excluding the primary antennae, which are approximately the same length as the adult's body length (Kensley and Williams 1986, p. 419). The species lacks large chelapeds (claws) (Kensley and Williams 1986, p. 426), which are a key diagnostic characteristic of all other known shrimp species. Vetericaris chaceorum is largely devoid of pigment and lacks eyes, although eyestalks are

present (Kensley and Williams 1986, p. 419).

Additional information on the descriptions of each species' occurrence can be found in the proposed (77 FR 63928, October 17, 2012) and final (78 FR 64638, October 29, 2013) listing rules for these species and in the proposed critical habitat rule (88 FR 18756, March 29, 2023).

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species. In 2019, jointly with the National Marine Fisheries Service, the Service issued a final rule that revised the regulations in 50 CFR part 424 regarding how we add, remove, and reclassify endangered and threatened species and the criteria for designating listed species' critical habitat (84 FR 45020; August 27, 2019).

Our analysis for this decision applied our current regulations, portions of which were last revised in 2019. Given that we proposed further revisions to these regulations on June 22, 2023 (88 FR 40764), we have also undertaken an analysis of whether the decision would be different if we were to apply those proposed revisions. We concluded that the decision would have been the sameif we had applied the proposed 2023 regulations. The analyses under both the regulations currently in effect and the regulations after incorporating the June 22, 2023, proposed revisions are included in our decision file.

Critical Habitat

Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, we designate a species' critical habitat concurrently with listing the species. Critical habitat is defined in section 3 of the Act as:

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

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

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

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

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

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

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Rather, designation requires that, where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency consult with the Service under section 7(a)(2) of the Act. If the action may affect the listed species itself (such as for occupied critical habitat), the Federal action agency would have already been required to consult with the Service even absent the critical habitat designation because of the requirement to ensure that the action is not likely to jeopardize the continued existence of the species. Even if the Service were to conclude after consultation that the proposed activity is likely to result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

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

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the species status report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the

species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of these species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species, and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or absence of a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

In this rule, the physical or biological features are based on the features of the six ecosystem types on which the 11 plant (*Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Schiedea hawaiiensis, Stenogyne cranwelliae*) and 1 animal (*Drosophila digressa*) species depend (see table 1, below). These six ecosystems are coastal, dry forest, mesic forest, wet forest, mesic grassland and shrubland, and wet grassland and shrubland; we summarize the descriptions of these ecosystems and our source for the descriptions below. The physical or biological features essential to the conservation of the species identified in this rule are those features required for the successful functioning of the ecosystem in which these species occur or have historically occurred (see table 2, below). Although critical habitat is identified for each species individually, we have found that the conservation of each depends, at least in part, on the successful functioning of the commonly shared ecosystem. Ecosystem parameters include elevation, precipitation, substrate, and associated native plant genera. These ecosystem parameters describe the species-specific physical or biological features of the functioning ecosystems on which these listed species depend. For example, the associated native plant genera described as physical or biological features for these 12 listed species are representative of the native plant genera that occur in the functioning ecosystems on which these 12 species depend, and as such, the occurrence of these native plant genera indicate functioning native ecosystems that provide the fundamental biological requirements for the listed species in these areas. Additionally, *Drosophila digressa* relies on native plant genera, specifically *Charpentiera, Rockia,* and *Ceodes,* as native plant host resources, and without which this species would be highly vulnerable to mortality, reproductive failure, and cyclical population variation related to fluctuations in breeding resources (Magnacca et al. 2008, p. 32).

Coastal (as Described by Kim et al. 2020, p. 2)

Coastal ecosystems are defined as near-shore areas that are impacted by the ocean and generally occur within 328 ft (100 m) of high tide up to 984 ft (300 m) in elevation. Coastal ecosystems are found on all the main Hawaiian Islands and include coastal dry herblands, coastal dry grasslands, coastal mixed communities, coastal dry shrublands, coastal dry forests, and coastal wet-mesic forests. Coastal substrate includes well-drained talus, calcareous slopes, and dunes. Annual precipitation ranges from less than 47 in (120 cm) in the coastal dry ecosystem to 47 to 98 in (120 to 250 cm) in the coastal mesic ecosystem, and to more than 98 in (250 cm) in the coastal wet ecosystem. *Bidens hillebrandiana* ssp. *hillebrandiana* is the only species addressed in this rule known to occupy a coastal ecosystem, and more

specifically the coastal wet ecosystem that receives higher rainfall.

Dry Forest (as Described by Javar-Salas et al. 2020, p. 2)

Dry forest ecosystems are found on all of the main Hawaiian Islands and include lowland dry forest and montane-alpine dry forest. Dry forest is found from 0 to 9,500 ft (0 to 2,900 m). Annual precipitation ranges from 12 to 79 in (30 to 200 cm). Substrates are generally well-drained, sandy loams from volcanic ash or cinder and weathered basaltic lava in lowland dry forest to well-drained, loams from volcanic ash, cinder, and weathered basaltic lava in montane-alpine dry forest. *Schiedea hawaiiensis* is the only species addressed in this rule known to occupy the dry forest ecosystem.

Mesic Forest (as Described by Lowe et al. 2020, pp. 2–7)

Mesic forest ecosystems include lowland mesic forest and montane subalpine mesic forest. Elevation ranges from 98 to 5,249 ft (30 to 1,600 m) in lowland mesic forest to 2,953 to 6,562 ft (900 to 2,000 m) in montane subalpine mesic forest. Annual precipitation ranges from 39 to 150 in (100 to 380 cm) in montane subalpine to 47 to 150 in (120 to 380 cm) in lowland mesic forest. Substrates are generally well-drained and include rocky, shallow, organic muck soils; steep rocky talus soils; shallow soils over weathered rock in steep gulches; deep soils over soft weathered rock; and gravelly alluvium. The plants *Cyrtandra nanawaleensis, Phyllostegia floribunda,* and *Pittosporum hawaiiense* addressed in this rule are found in the mesic forest ecosystem. The picture-wing fly, *Drosophila digressa,* addressed in this rule is also found in the mesic forest ecosystem.

Wet Forest (as Described by Clark et al. 2020, p. 2)

Wet forest ecosystems include lowland rainforest, montane rainforest, and montane cloud forest. Elevation ranges from 328 to 3,937 ft (100 to 1,200 m) in lowland rainforest; 2,700 to 7,218 ft (823 to 2,200 m) in montane rainforest; and 2,461 to 6,070 ft (750 to 1,830 m) in montane cloud forest. Annual precipitation is greater than 98 in (250 cm). Substrates range from very weathered soils to rocky substrate with classes of undeveloped and developed soil substrates formed from basalt lava. The plants *Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Melicope remyi, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* addressed in this rule are found in the wet forest ecosystem. *Drosophila digressa* is also found in the wet forest ecosystem.

Mesic Grassland and Shrubland (as Described by Ball et al. 2020, p. 2)

Mesic grassland and shrubland ecosystems include lowland mesic shrubland, subalpine mesic shrubland, montane-subalpine mesic grassland, and lowland mesic grassland. Elevation ranges from 98 to 7,546 ft (30 to 2,300 m). Annual precipitation ranges from 39 to 98 in (100 to 250 cm). Substrates generally include shallow soils that frequently dry with rocky outcrops. *Cyrtandra nanawaleensis* is the only species addressed in this rule known to occupy the mesic grassland and shrubland ecosystem.

Wet Grassland and Shrubland (as Described by Nelson et al. 2020, p. 3)

Wet grassland and shrubland ecosystems include native wet sedge and grassland and native wet cliff and crest shrubland. Elevation ranges from 656 to 2,953 ft (200 to 900 m). Annual precipitation ranges from 98 to 197 in (250 to 500 cm). Substrates range from older, weathered soils to younger, rocky substrates. The plants *Cyanea tritomantha* and *Phyllostegia floribunda* addressed in this rule are found in the wet grassland and shrubland ecosystem.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the 12 species from studies of the species' habitat, ecology, and life history as described below. Additional information about the ecosystems containing these physical or biological features and descriptions of each species' occurrence within these ecosystems can be found in the proposed (77 FR 63928, October 17, 2012) and final (78 FR 64638, October 29, 2013) listing rules and the proposed critical habitat rule (88 FR 18756, March 29, 2023) for these species. Each species identified in this rule requires the physical or biological features for each ecosystem in which that species occurs, as noted below in table 1. Table 2, below, identifies the physical or biological features of a functioning ecosystem for each of the ecosystem types identified in this rule. The physical or biological features are defined here by elevation, annual levels of precipitation, substrate type, and the characteristic native plant genera that are found in the canopy, subcanopy, and understory levels of the vegetative community where applicable. Due to our limited knowledge of the specific life-history requirements for the species that are little-studied and occur in remote and inaccessible areas, the physical or biological features described in this document that provide for the successful function of the ecosystem that is essential to the conservation of the species represents the best, and, in many cases, the only, scientific information available. Accordingly, the physical or biological features of a functioning ecosystem are, at least in part, the physical or biological features essential to the conservation of these 12 species.

TABLE 1—TWELVE SPECIES AND APPLICABLE ECOSYSTEMS

[Note: All species, except for *Bidens hillebrandiana* ssp. *hillebrandiana* and *Schiedea hawaiiensis* are found in multiple ecosystems]

Ecosystem	Species
Coastal	*Bidens hillebrandiana* ssp. *hillebrandiana*.
Dry Forest	*Schiedea hawaiiensis*.
Mesic Forest	*Cyrtandra nanawaleensis, Phyllostegia floribunda, Pittosporum hawaiiense,* and *Drosophila digressa*.
Wet Forest	*Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Melicope remyi, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa*.
Mesic Grassland and Shrubland	*Cyrtandra nanawaleensis*.
Wet Grassland and Shrubland	*Cyanea tritomantha, Phyllostegia floribunda*.

TABLE 2—PHYSICAL OR BIOLOGICAL FEATURES FOR EACH ECOSYSTEM UPON WHICH THE 12 SPECIES DEPEND
[Read in association with table 1]

Ecosystem	Elevation	Annual precipitation	Substrate	Contain one or more of these associated native plant genera		
				Canopy	Subcanopy	Understory
Coastal	<984ft (<300 m)	<47 to >98 in (<120 cm to >250 cm).	well-drained talus, calcareous slopes, dunes.	*Diospyros, Metrosideros, Myoporum, Pritchardia.*	*Chenopodium, Gossypium, Heliotropium, Santalum, Scaevola.*	*Eragrostis, Sesuvium, Sida, Sporobolus.*
Dry Forest	<9,500 ft (<2,900 m).	<79 in (<200 cm).	well-drained, sandy loams or loams from volcanic ash or cinder; weathered basaltic lava.	*Acacia, Colubrina, Diospyros, Erythrina, Melicope, Metrosideros, Myoporum, Myrsine, Sophora.*	*Achyranthes, Euphorbia, Leptecophylla, Nototrichium.*	*Dodonaea, Doryopteris, Heteropogon, Pellaea.*
Mesic Forest	<6,562 ft (<2,000 m).	39–150 in (100–380 cm).	rocky, shallow, organic muck soils; rocky talus soils; shallow soils over weathered rock; deep soils over soft weathered rock; gravelly alluvium.	*Acacia, Antidesma, Charpentiera, Chrysodracon, Metrosideros, Myrsine, Nestegis, Pisonia, Santalum.*	*Coprosma, Freycinetia, Leptecophylla, Myoporum, Pipturus, Rubus, Sadleria, Sophora.*	*Ctenitis, Doodia, Dryopteris, Pelea, Sadleria.*
Wet Forest	<7,218 ft (<2,200 m).	>98 in (≤ 250 cm).	very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.	*Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*	*Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*	*Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*
Mesic Grassland and Shrubland.	98–7,546 ft (30–2,300 m).	39–98 in (100–250 cm).	shallow soils that frequently dry with rocky outcrops.	*Coprosma, Metrosideros, Wilkesia.*	*Dodonaea, Dubautia, Leptecophylla, Osteomeles, Sadleria, Vaccinium.*	*Bidens, Carex, Deschampsia, Dicranopteris, Dryopteris, Eragrostis, Euphorbia, Lipochaeta.*
Wet Grassland and Shrubland.	656–2,953 ft (200–900 m).	98–197 in (250–500 cm).	older, weathered soils to younger, rocky substrates.	*Ilex, Kadua, Melicope, Metrosideros, Myrsine.*	*Cibotium, Clermontia, Dubautia, Freycinetia, Hydrangea, Lobelia, Pipturus, Touchardia, Urera, Vaccinium.*	*Carex, Cladium, Deschampsia, Dicranopteris, Eragrostis, Peperomia, Phyllostegia, Scaevola.*

The physical or biological features identified in this rule take into consideration the ecosystem types in which each species occurs, as described above. We considered the current population status of each species, to the extent it is known, and assessed its status relative to the recovery objectives for that species, in terms of population goals (numbers of populations and individuals in each population, which contributes to population resiliency) and essential distribution (whether the populations occur in habitats representative of the species' historical geographical and ecological distribution, and are sufficiently redundant to withstand the loss of some populations over time). This assessment informed us as to whether the species requires space for population growth and expansion in areas occupied at the time of listing, or whether additional areas unoccupied at the time of listing may be required for the reestablishment of populations to achieve recovery.

Some of the species addressed in this rule occur in more than one ecosystem. We describe the physical or biological features for these species separately for each ecosystem in which they occur. We took this approach because each species requires a different suite of environmental conditions depending upon the ecosystem in which it occurs. For example, *Cyrtandra nanawaleensis* will occur in association with different native plant species, depending on the mesic forest, wet forest, or mesic grassland and shrubland ecosystem type where it is found. Each of the physical or biological features described in each ecosystem in which the species occurs are essential to the conservation of the species, which includes the ability to support the geographical and ecological distribution across the different ecosystem types where the species occurs. Each physical or biological feature is also essential to retaining the genetic representation that allows the species to successfully adapt to different environmental conditions in various native ecosystems. Although some of these species occur in multiple native ecosystems, their declining abundance in the face of ongoing threats, such as increasing numbers of nonnative plant competitors, indicates that they are not such broad habitat generalists as to be able to persist in highly altered habitats. Based on an analysis of the best available scientific information, functioning native ecosystems provide the fundamental biological requirements for the narrow-range, island-endemic species that are addressed in this rule.

We offer some examples to help readers understand our approach to describing the physical or biological features for each species. For example, to understand the physical or biological features for the plant *Bidens hillebrandiana* ssp. *hillebrandiana,* first look at table 1 and see that *B. hillebrandiana* ssp. *hillebrandiana* depends on the coastal ecosystem. Then table 2 indicates that the physical or biological features in the coastal ecosystem include elevations of less than 984 ft (300 m); annual precipitation ranges from less than 47 in (120 cm) to more than 98 in (250 cm); well-drained talus, calcareous slopes, and dunes; and one or more genera of the subcanopy and understory plants *Chenopodium, Eragrostis, Gossypium, Heliotropium, Santalum, Scaevola, Sesuvium, Sida,* and *Sporobolus,* and one or more of the genera of the canopy species *Diospyros, Metrosideros, Myoporum,* and *Pritchardia.* The specific physical or biological features for *B. hillebrandiana*

ssp. *hillebrandiana* are intrinsically tied to the coastal ecosystem. The physical or biological features of the coastal ecosystem best approximate the physical or biological features for *B. hillebrandiana* ssp. *hillebrandiana.* Thus, we use the physical and biological features provided in the ecosystem in which *B. hillebrandiana* ssp. *hillebrandiana* is found as the physical and biological features for *B. hillebrandiana* ssp. *hillebrandiana.*

As another example, table 1 indicates the physical or biological features for the plant *Phyllostegia floribunda* include the ecosystem-level physical or biological features for the mesic forest, wet forest, and wet grassland and shrubland ecosystems. The physical or biological features for *P. floribunda* are thus composed of the physical or biological features for each of the three ecosystems it occupies, as described in table 2 for the mesic forest, wet forest, and wet shrubland and grassland ecosystems. Table 1 is read in a similar fashion in conjunction with table 2 to describe the physical or biological features for each of the 12 species for which we are designating critical habitat.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The following discussion of special management needs is applicable to each of the 12 species on the island of Hawai'i for which we are designating critical habitat.

For the 11 plant species and *Drosophila digressa,* we have determined that the features essential to their conservation are those required for the successful functioning of the ecosystem in which they occur (see tables 1 and 2, above); conversely, threats that act at the ecosystem level also act at the species level. Special management considerations or protections may be required throughout designated critical habitat areas to avoid further degradation or destruction of the physical or biological features essential to the 12 species' conservation. Habitat degradation (resulting from, for example, trampling and herbivory by introduced ungulates, fire, drought, and habitat modification by invasive plants) is the greatest threat to these 12 species, and this threat acts at the ecosystem level. Threats specific to *Drosophila digressa* habitat include loss or lack of host plants from ungulates, drought, fire, alteration of microclimate by invasive plants or the plant disease referred to as rapid a death (ROD) (78 FR 64638, October 29, 2013; Service 2023a, pp. 21–28). Some of these threats may be addressed by special management considerations or protection, while others (*e.g.,* sea level rise, hurricanes, drought, volcanic eruption) are beyond the control of landowners and managers. For a more detailed description of threats, please see the proposed listing rule (77 FR 63928 at 63941–63974, October 17, 2012), the final listing rule (78 FR 64638 at 64653–64686, October 29, 2013), and the draft recovery plan (Service 2022a, entire).

While the 12 species share many threats, impacts to individual species and the actions needed to eliminate or manage the threats may differ. Management activities that could minimize or ameliorate these threats include, but are not limited to, ungulate removal and exclusion fencing; control or eradication of significant habitat-modifying, invasive plants; fire management planning and wildfire response; and measures to reduce of the spread of ROD and other plant pathogens. Management activities that could minimize or ameliorate threats specific to *Drosophila digressa* include control measures to reduce and eradicate invasive invertebrates, such as wasps and ants. These management actions would result in the protection of areas providing habitat for the 12 species.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and refer to these areas as occupied habitat. We also review available information pertaining to habitat requirements of the species in areas outside the geographical area occupied by the species at the time of listing for consideration as critical habitat, and these areas are referred to as unoccupied habitat. We will designate as critical habitat specific areas outside the geographical area occupied by the species only upon a determination that such areas are essential for the conservation of the species. We will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied would be inadequate to ensure the conservation of the species. In addition, for an unoccupied area to be considered essential, we must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

We are designating both occupied and unoccupied critical habitat for eight species (*Drosophila digressa, Cyanea marksii, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae*). We are not designating any occupied areas as critical habitat for *Schiedea hawaiiensis* because the single area known to be occupied by the species at the time of listing is exempt from designation (see Exemptions, below, for more information). For *Bidens hillebrandiana* ssp. *hillebrandiana, Cyrtandra nanawaleensis,* and *Cyrtandra wagneri,* we are not designating any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the definition of critical habitat for these species; no unoccupied areas had at least one physical or biological feature essential to the conservation of the species and a reasonable certainty of contributing to conservation.

Except for the designated critical habitat in Unit 55 for *Schiedea hawaiiensis,* all unoccupied critical habitat areas overlap entirely with a geographical area for which we are designating occupied critical habitat for at least one of the other species that are the subjects of this rule. The unoccupied critical habitat in Unit 55 for *Schiedea hawaiiensis* has no overlap in geographic occurrence or range with the other species addressed in this rule. We note that the new plant critical habitat Unit 56 is not occupied by either of the plant species for which it is designated (*Cyanea marksii* and *Schiedea diffusa* ssp. *macraei*) or any of the other nine plant species that are part of this critical habitat designation, but Unit 56 exists entirely within the boundaries of *Drosophila digressa*—Unit 6, which is occupied by *Drosophila digressa.* We are designating areas outside the geographical area occupied by nine species (*Drosophila digressa, Cyanea marksii, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea*

diffusa ssp. *macraei, Stenogyne cranwelliae,* and *Schiedea hawaiiensis*) due to small population sizes, few individuals, or reduced geographic range, which make these species vulnerable to stochastic events. Many of these species are so rare in the wild that they are at a high risk of extirpation or even extinction from various catastrophic events, such as hurricanes or landslides. Therefore, supporting resiliency and redundancy in these species through the establishment of multiple, robust populations is a key component of conservation of the species (Service 2022a, pp. 29–30, 35, 39, 48–49). A designation limited to occupied areas would be inadequate to ensure the conservation of these species. Areas that may have been unoccupied at the time of listing, together with areas occupied at the time of listing, are reasonably certain to provide some or all of the habitat necessary for the expansion of existing wild populations and reestablishment of wild populations within the historical range of the species to achieve a level that could approach recovery. The best available scientific information suggests that the ecosystems in the unoccupied areas in which we are designating critical habitat provide one or more of the physical or biological features that support life-history requirements of these nine species, and thus these unoccupied areas are considered habitat for the conservation of these nine species. These areas support recovery in the case of stochastic events that otherwise have potential to eliminate a species from locations where it is currently found, and some species are only known from one location. We find, therefore, that designation of these unoccupied areas as critical habitat is essential for the conservation of the species. Designating unoccupied areas as critical habitat for these species also promotes conservation actions to restore their historical, geographical, and ecological representation, which are necessary for their recovery.

In this rule, we designate critical habitat for 12 species in 21 distinct areas that include 42 critical habitat units, with animal and plant units identified separately. Each critical habitat unit contains all or some of the physical or biological features essential to the conservation of those individual species that occupy that particular unit, or areas essential for the conservation of those species identified that do not presently occupy that particular unit. The critical habitat for all species includes the functioning ecosystems on which they depend; thus, for those species with life-history requirements that can be supported in multiple ecosystem types, we have identified areas of critical habitat in multiple ecosystem types. For example, the plant *Cyrtandra nanawaleensis* is found in multiple critical habitat units across three ecosystem types: mesic forest, wet forest, and mesic grassland and shrubland.

Because we have determined that the features essential to the conservation of the 12 species are those required for the successful functioning of the ecosystems in which they respectively occur, we grouped species by the commonly shared ecosystem type to delineate critical habitat units. We used similar methods to identify critical habitat unit boundaries for nine plant species: *Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.* These nine species were considered together because spatial data used for delineating critical habitat are similar among these species, and these species all occur within mesic to wet ecosystems, whereas the remaining two plant species do not (see table 1, above). We considered each species separately within their shared dependence on the functioning ecosystems they have in common. We used separate methods to identify critical habitat unit boundaries for each of the remaining three species: *Bidens hillebrandiana* ssp. *hillebrandiana, Schiedea hawaiiensis,* and *Drosophila digressa. Bidens hillebrandiana* ssp. *hillebrandiana* and *Schiedea hawaiiensis* each occur in an ecosystem type not shared with any of the other 12 species, and *Drosophila digressa* was considered separately because of differences in taxonomy and life history from the plants. Critical habitat boundaries for all species were delineated to clearly depict and promote conservation of these species by identifying the functioning ecosystem on which they depend. Ecosystem types that support the species addressed here but that do not form a contiguous area are divided geographically into separate units. In units consisting of multiple ecosystem types, if a species' physical or biological features are provided by one of the ecosystem types, we designate the entire area as critical habitat for that species. We took this approach because within these units, ecosystem types are patchily distributed at a relatively fine resolution, intermingled, and can be dynamic on a relatively short timescale in their distribution within the critical habitat area.

To delineate the critical habitat units, we relied on an overall conservation strategy in which each of the 12 species was considered separately using a common approach for 9 plant species, and a separate approach for the remaining 2 plant species and *Drosophila digressa.* The goal of the conservation strategy was to identify the specific areas for each species that provide essential physical or biological features without which rangewide resiliency, redundancy, and representation could not be achieved. The conservation strategy considered (1) historical and current distribution of each of the 12 species; (2) assessments of resiliency, redundancy, and representation for each species from the most recent species reports (Service 2023a-n); and (3) recovery planning efforts (Service 2022a, entire). Some of the critical habitat for these 12 species overlies critical habitat already designated for other species on the island of Hawai'i.

In summary, we completed the following basic steps to delineate critical habitat (specific methods follow below):

(1) We compiled the best scientific data available on observations and distributions of the 12 species that were extant at the time of listing;

(2) We compiled all available location and landcover data, including ecosystem type, within the ranges of the 12 species;

(3) We identified areas containing the physical or biological features that may require special management considerations or protection;

(4) We circumscribed boundaries of critical habitat units based on the above information; and

(5) We removed, to the extent practicable, all areas that did not have the specific physical or biological feature components, and therefore are not considered essential to the conservation of one or more of these 12 species.

Based on these five steps, for areas within and outside the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries using the following methods:

(1) Species observation and distribution data sources: We obtained observational and distributional data to include in our Geographic Information System (GIS) database for each of the 12 species including the known locations of the species from the Hawai'i Biodiversity Mapping Program (HBMP) database (HBMP 2010a, entire; HBMP

2010b, entire; HBMP 2010c, entire; HBMP 2010d, entire; HBMP 2010e, entire; HBMP 2010f, entire; HBMP 2010g, entire; HBMP 2010h, entire), the Plant Extinction Prevention Program (PEPP) database (PEPP 2021, unpublished), and our own rare plant database. We also obtained and compiled species information from the plant database housed at National Tropical Botanical Garden (*https://ntbg.org/database/herbarium/*). We used Hawai'i Biodiversity Mapping Program's Geographic reference areas for the Hawaiian Islands in conjunction with known species' location data (Kam 2017, p. 1; Hawai'i Rare Plant Restoration Group 2020, p. 2). For plants, we obtained and compiled species range maps, as determined by plant species ranges in the Hawaiian Islands (Price et al. 2012, entire), and our own plant species range layer adapted from Price et al. 2012 (Service 2022b-l, entire). For *Drosophila digressa,* we created our own potential species range layer using the U.S. Geological Survey's (USGS's) Carbon Assessment Landcover data of 2017 for mesic and wet forest habitats (Selmants et al. 2017, entire; Service 2023a, entire) and the known elevational range of the species, which is between 2,000 to 4,500 ft (600 to 1,400 m). Lastly, we obtained recent biological surveys and reports and discussed that information with qualified individuals familiar with these 12 species and their ecosystems.

We used current and historical species distribution information to develop initial critical habitat boundaries in each of the six ecosystems that would provide for the conservation of the 12 species. The initial boundaries were superimposed over digital topographic maps of the island of Hawai'i and further evaluated. In general, land areas that were identified as highly degraded were removed from the critical habitat units, and natural or constructed features (*e.g.,* ridge lines, valleys, streams, coastlines, roads, lava flows, obvious land features, etc.) were used to delineate the critical habitat boundaries.

(2) Identified areas containing physical or biological features: We obtained and compiled island-wide elevation, annual precipitation, soil substrate, and associated native plant genera data sources (Gagne and Cuddihy 1999, pp. 45–114; LANDFIRE 2016, pp. 1177–1242; Ball et al. 2020, p. 2; Clark et al. 2020, p. 2; Javar-Salas et al. 2020, p. 2; Kim et al. 2020, p. 2; Lowe et al. 2020, pp. 2–7; Nelson et al. 2020, p. 3; Giambelluca et al. 2013, entire; Price and Jacobi 2012, entire). We evaluated areas currently occupied by each species and whether they contain the physical or biological features essential to the conservation of the species and which may require special management considerations or protection. We considered the degree to which the physical or biological features were present or absent in areas as an indication of the successful functioning of the habitat.

(3) Landcover and ecosystem data sources: We obtained and compiled landcover and ecosystem data from the island-wide GIS coverage including USGS Carbon Assessment Landcover data of 2017 (Selmants et al. 2017, entire) and ArcGIS Esri World Imagery of 2022 (Esri 2023, entire); 1:24,000 scale digital raster graphics of USGS topographic quadrangles; and geospatial data sets associated with parcel data from Hawai'i County (Hawaii Statewide GIS Program 2022, entire). We evaluated areas currently occupied by each species. When a species occurs in more than one ecosystem type, we include the full range of ecosystem types within that species' range. For example, *Phyllostegia floribunda* is known from three of the six ecosystem types addressed in this rule: mesic forest, wet forest, and wet grassland and shrubland ecosystem types.

(4) Circumscribed boundaries of potential critical habitat units: We considered several factors in the selection of specific boundaries for critical habitat for the 12 species. We determined critical habitat unit boundaries taking into consideration the information on known past and present locations of the species, landcover and ecosystem data sources by USGS Carbon Assessment Landcover Data (Selmants et al. 2017, entire), recovery areas described by the species' draft recovery plan, projections of geographic ranges of Hawaiian plant species (Price et al. 2012, entire; Service 2022b–l, entire) and *Drosophila digressa* (Service 2023a, entire), and adequate habitat to allow for increases in numbers of individuals and for expansion of populations to provide for the minimum numbers required to reach delisting goals (as described in the draft recovery plan (Service 2022a, entire)). Critical habitat boundaries for all species were delineated to promote the conservation of these species by identifying the functioning ecosystems on which they depend.

(5) Removed areas lacking the identified physical or biological features: When determining critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack the physical or biological features necessary for these 12 species. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations (CFR) may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this rule have been excluded by text in the rule and are not designated as critical habitat. Therefore, a Federal action involving these lands will not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action will affect the physical or biological features in the adjacent critical habitat.

We are designating as critical habitat lands that we have determined are occupied at the time of listing and that contain one or more of the physical or biological features that are essential to support life-history processes of the species. We have determined that occupied areas are inadequate to ensure the conservation of some of the species; therefore, we have also identified, and designate as critical habitat, unoccupied areas that are essential for the conservation of nine of the species (see Final Critical Habitat Designation, below). We have determined that these units are habitat for these nine species and will both contribute to the conservation of the species and contain at least one physical or biological feature essential to the conservation of the species.

Units are designated based on one or more of the physical or biological features being present to support the life-history processes for 1 or more of the 12 species for which we designate critical habitat. Some units contain all of the identified physical or biological features and support multiple life-history processes. Some units contain only some elements of the physical or biological features necessary to support the species' particular use of that habitat.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–R1–ES–2023–0017.

Final Critical Habitat Designation

We are designating approximately 119,326 ac (48,289 ha) as critical habitat in 21 distinct areas that include 42 critical habitat units, with 9 animal and 33 plant units identified separately, for *Drosophila digressa, Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Schiedea hawaiiensis,* and *Stenogyne cranwelliae.* The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for each species. Table 3 shows the critical habitat units and the approximate area of each unit by landowner type.

Within the 21 distinct areas, areas of critical habitat for *Drosophila digressa* are described as 9 sequential numbered units, whereas areas of critical habitat for plants are described as 20 sequential numbered sections that are then split into 1 or more units, based on whether they overlap with existing designated critical habitat for other plant species on the island of Hawai'i. Some of the critical habitat for *Drosophila digressa* overlays critical habitat already designated for plant species; however, critical habitat designations for wildlife species at 50 CFR 17.95 are organized differently than critical habitat designations for plant species on the island of Hawai'i at 50 CFR 17.99. Therefore, the critical habitat for *Drosophila digressa* is not presented as being part of any of the existing critical habitat units for plant species. Conversely, for Hawaiian plants only, areas of a plant section that overlay existing Hawaiian plant critical habitat units are assigned to that existing critical habitat unit name. Areas of a plant section that do not overlay existing Hawaiian plant critical habitat are assigned a sequential new critical habitat unit number. This distinction between existing and newly designated critical habitat areas is necessary in order to be consistent with the critical habitat unit numbering system we established earlier for plants on the island of Hawai'i (see 50 CFR 17.99(k)). We provide the critical habitat plant section numbers, where applicable, as well as unit numbers and the corresponding map numbers that appear at 50 CFR 17.99 for ease of reference in the CFR. All units in the designation, with the exception of Unit 55 for *Schiedea hawaiiensis* within Section 19, are considered occupied at the time of listing (see 78 FR 64638; October 29, 2013) by 1 or more of the 12 species for which we are designating critical habitat (see table 4, below). Of the 21 distinct areas for which we are designating critical habitat in this rule, 12 include animal units or plant sections that are both occupied and unoccupied for 2 or more of the 12 Hawai'i island species.

The areas we designate as critical habitat are located in six ecosystem types: (1) coastal, (2) dry forest, (3) mesic forest, (4) wet forest, (5) mesic grassland and shrubland, and (6) wet grassland and shrubland. Critical habitat designations for plants and animals are published in separate sections of the CFR; however, the critical habitat for the 11 plants and *Drosophila digressa* overlap each other in many areas on the island of Hawai'i. For example, ''*Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 1'' and ''*Drosophila digressa*—Unit 1'' overlap entirely within the same geographic area. Therefore, because the section and unit boundaries are the same, we describe them together to avoid redundancy and reduce publication costs for this rule, as indicated by ''and'' following the section name in the headings of the section and unit descriptions, below.

TABLE 3—CRITICAL HABITAT UNITS BY ECOSYSTEM, LAND OWNERSHIP, AND SIZE

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

Animal unit	Plant section	Plant unit	Federal (ac (ha))	State (ac (ha))	Private/other (ac (ha))	Total (ac (ha))
Wet Forest*						
Drosophila digressa—Unit 1.	*Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 1.	Unit 3	3,549 (1,436)	7,963 (3,223)	547 (221)	12,059 (4,880)
		Unit 52	549 (222)	2,681 (1,085)	425 (172)	3,656 (1,479)
Subtotal	.....	.....	4,098 (1,658)	10,644 (4,308)	972 (394)	15,714 (6,359)
Drosophila digressa—Unit 7.	*Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 4.	Unit 15	.....	182 (73)	.....	182 (73)
		Unit 39	.....	997 (403)	167 (68)	1,164 (471)
Subtotal	.....	.....	.....	1,179 (477)	167 (68)	1,346 (545)
Drosophila digressa—Unit 8.	*Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 5.	Unit 15	.....	55 (22)	72 (29)	127 (51)
		Unit 38	.....	297 (120)	237 (96)	534 (216)
Subtotal	.....	.....	.....	352 (142)	309 (125)	661 (267)
	Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. *macraei, Stenogyne cranwelliae*—Section 6.	Unit 16	.....	156 (63)	.....	156 (63)
		Unit 40	.....	1,190 (482)	52 (21)	1,243 (503)
Subtotal	.....	.....	.....	1,347 (545)	52 (21)	1,399 (566)
Drosophila digressa—Unit 2.	*Cyanea tritomantha, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 11.	Unit 29	.....	494 (200)	.....	494 (200)
		Unit 30	7,232 (2,927)	6,498 (2,630)	<1 (<1)	13,730 (5,556)
		Unit 51	643 (260)	16,905 (6,841)	226 (91)	17,774 (7,193)
Subtotal	.....	.....	7,875 (3,187)	23,897 (9,671)	226 (91)	31,998 (12,949)

TABLE 3—CRITICAL HABITAT UNITS BY ECOSYSTEM, LAND OWNERSHIP, AND SIZE—Continued
[Area estimates reflect all land within critical habitat unit boundaries]

Animal unit	Plant section	Plant unit	Federal (ac (ha))	State (ac (ha))	Private/other (ac (ha))	Total (ac (ha))
Drosophila digressa—Unit 9.	*Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 12.	Unit 37	1,906 (771)		<1 (<1)	1,906 (771)
Subtotal			1,906 (771)		<1 (<1)	1,906 (771)
Drosophila digressa—Unit 5.	*Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 13.	Unit 41		411 (166)	3,001 (1,214)	3,412 (1,381)
Subtotal				411 (166)	3,001 (1,214)	3,412 (1,381)
	Cyrtandra nanawaleensis—Section 15	Unit 47		274 (111)		274 (111)
Subtotal				274 (111)		274 (111)
	Cyrtandra nanawaleensis—Section 16	Unit 48		586 (237)	3 (1)	589 (238)
Subtotal				586 (237)	3 (1)	589 (238)
Drosophila digressa—Unit 6.	*Cyanea marksii, Schiedea diffusa* ssp. *macraei*—Section 20.	Unit 56		224 (91)		224 (91)
Subtotal				224 (91)		224 (91)
Coastal*						
	Bidens hillebrandiana ssp. *hillebrandiana*—Section 2.	Unit 6		2 (1)		2 (1)
		Unit 53		76 (31)	78 (32)	154 (62)
Subtotal				78 (32)	78 (32)	156 (63)
Wet Forest and Wet Grassland and Shrubland*						
	Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. *macraei, Stenogyne cranwelliae*—Section 3.	Unit 8		6,805 (2,754)		6,805 (2,754)
		Unit 9			1 (<1)	1 (<1)
		Unit 54		5,855 (2,369)	90 (36)	5,945 (2,406)
Subtotal				12,660 (5,123)	91 (37)	12,751 (5,160)
	Phyllostegia floribunda, Pittosporum hawaiiense—Section 7.	Unit 23	9 (4)			9 (4)
		Unit 45	5,494 (2,223)			5,494 (2,223)
Subtotal			5,503 (2,227)			5,503 (2,227)
	Cyrtandra nanawaleensis, Phyllostegia floribunda—Section 10.	Unit 28		155 (63)		155 (63)
		Unit 46		12,212 (4,942)	7 (3)	12,219 (4,945)
Subtotal				12,368 (5,005)	7 (3)	12,374 (5,008)
Wet Forest and Mesic Forest*						
	Cyanea tritomantha, Pittosporum hawaiiense, Schiedea diffusa ssp. *macraei, Stenogyne cranwelliae*—Section 8.	Unit 24	1,956 (792)			1,956 (792)
		Unit 44	322 (130)	5,561 (2,251)		5,884 (2,381)
Subtotal			2,278 (922)	5,561 (2,251)		7,840 (3,173)
	Pittosporum hawaiiense, Schiedea diffusa ssp. *macraei, Stenogyne cranwelliae*—Section 9.	Unit 24	36 (15)	65 (26)		101 (41)
		Unit 43	1,693 (685)	4,180 (1,691)		5,872 (2,376)
Subtotal			1,729 (700)	4,244 (1,718)		5,973 (2,417)
Drosophila digressa—Unit 3.	*Cyanea tritomantha, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae*—Section 14.	Unit 42	8,773 (3,550)	8 (3)		8,781 (3,554)
Subtotal			8,773 (3,550)	8 (3)		8,781 (3,554)
Wet Forest, Mesic Forest, and Mesic Grassland and Shrubland*						
	Cyrtandra nanawaleensis—Section 17	Unit 49		868 (351)	6 (3)	875 (354)
Subtotal				868 (351)	6 (3)	875 (354)
	Cyrtandra nanawaleensis—Section 18	Unit 50		562 (227)		562 (227)
Subtotal				562 (227)		562 (227)
Dry Forest*						
	Schiedea hawaiiensis—Section 19	Unit 55		6,822 (2,761)		6,822 (2,761)

TABLE 3—CRITICAL HABITAT UNITS BY ECOSYSTEM, LAND OWNERSHIP, AND SIZE—Continued

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

Animal unit	Plant section	Plant unit	Federal (ac (ha))	State (ac (ha))	Private/other (ac (ha))	Total (ac (ha))
Subtotal				6,822 (2,761)		6,822 (2,761)
Mesic Forest*						
Drosophila digressa—Unit 4.				167 (67)		167 (67)
Subtotal				167 (67)		167 (67)
Total			32,162 (13,015)	82,252 (33,286)	4,913 (1,988)	119,326 (48,289)

Note: Area sizes may not sum due to rounding.

*Ecosystem subheadings indicate all of the ecosystems that can be found in each unit, but not every species for which each unit is designated is found in every ecosystem found in the unit (see table 1 for the ecosystems within each species may be found).

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TABLE 4—CRITICAL HABITAT UNITS FOR 11 HAWAI'I ISLAND PLANT SPECIES.
[O=occupied critical habitat, UN=unoccupied critical habitat.]

Plant Section	Plant Unit	*Bidens hillebrandiana* ssp. *hillebrandiana*	*Cyanea marksii*	*Cyanea tritomantha*	*Cyrtandra nanawaleensis*	*Cyrtandra wagneri*	*Melicope remyi*	*Phyllostegia floribunda*	*Pittosporum hawaiiense*	*Schiedea diffusa* ssp. *macraei*	*Schiedea hawaiiensis*	*Stenogyne cranwelliae*	Corresponding critical habitat map in the Code of Federal Regulations (CFR)
1	3	-	-	O	-	O	O	O	UN	UN	-	O	11a
	52	-	-	O	-	O	O	O	UN	UN	-	O	119
2	6	O	-	-	-	-	-	-	-	-	-	-	24a
	53	O	-	-	-	-	-	-	-	-	-	-	120
3	8	-	-	O	-	-	UN	UN	O	O	-	O	27a
	9	-	-	O	-	-	UN	UN	O	O	-	O	38a
	54	-	-	O	-	-	UN	UN	O	O	-	O	121
4	15	-	O	-	-	-	-	O	O	UN	-	UN	58a
	39	-	O	-	-	-	-	O	O	UN	-	UN	108
5	15	-	O	-	-	-	-	UN	UN	UN	-	UN	58a
	38	-	O	-	-	-	-	UN	UN	UN	-	UN	107
6	16	-	O	-	-	-	-	O	UN	UN	-	UN	60a
	40	-	O	-	-	-	-	O	UN	UN	-	UN	109
7	23	-	-	-	-	-	-	O	O	-	-	-	74a
	45	-	-	-	-	-	-	O	O	-	-	-	114
8	24	-	-	O	-	-	-	-	O	O	-	UN	78a
	44	-	-	O	-	-	-	-	O	O	-	UN	113
9	24	-	-	-	-	-	-	-	O	O	-	UN	78a
	43	-	-	-	-	-	-	-	O	O	-	UN	112
10	28	-	-	-	O	-	-	O	-	-	-	-	89a
	46	-	-	-	O	-	-	O	-	-	-	-	115
11	29	-	-	O	-	-	-	O	O	O	-	UN	91a
	30	-	-	O	-	-	-	O	O	O	-	UN	98a
	51	-	-	O	-	-	-	O	O	O	-	UN	118
12	37	-	O	-	-	-	-	UN	UN	UN	-	UN	106
13	41	-	O	-	-	-	-	O	O	UN	-	UN	110
14	42	-	-	UN	-	-	-	UN	O	O	-	UN	111
15	47	-	-	-	O	-	-	-	-	-	-	-	116
16	48	-	-	-	O	-	-	-	-	-	-	-	116
17	49	-	-	-	O	-	-	-	-	-	-	-	117
18	50	-	-	-	O	-	-	-	-	-	-	-	117
19	55	-	-	-	-	-	-	-	-	-	UN	-	122
20	56	-	UN	-	-	-	-	-	-	UN	-	-	123

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TABLE 5—CRITICAL HABITAT UNITS FOR DROSOPHILA DIGRESSA
[Picture-wing fly]

Critical habitat unit	Occupied/unoccupied	Corresponding critical habitat map in the Code of Federal Regulations (CFR)
Drosophila digressa—Unit 1	Unoccupied	*Drosophila digressa*—Hawai'i Island, HI—Unit 1.

TABLE 5—CRITICAL HABITAT UNITS FOR DROSOPHILA DIGRESSA—Continued

[Picture-wing fly]

Critical habitat unit	Occupied/unoccupied	Corresponding critical habitat map in the Code of Federal Regulations (CFR)
Drosophila digressa—Unit 2	Occupied	*Drosophila digressa*—Hawai'i Island, HI—Unit 2.
Drosophila digressa—Unit 3	Unoccupied	*Drosophila digressa*—Hawai'i Island, HI—Unit 3.
Drosophila digressa—Unit 4	Occupied	*Drosophila digressa*—Hawai'i Island, HI—Unit 4.
Drosophila digressa—Unit 5	Unoccupied	*Drosophila digressa*—Hawai'i Island, HI—Unit 5, Unit 6, Unit 7, Unit 8, Unit 9.
Drosophila digressa—Unit 6	Occupied	
Drosophila digressa—Unit 7	Unoccupied	
Drosophila digressa—Unit 8	Unoccupied	
Drosophila digressa—Unit 9	Unoccupied	

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat, for each of the 12 Hawai'i Island species, below.

Descriptions of Critical Habitat

We describe each section and unit separately, below, but first describe the common rationale for designating areas of critical habitat as occupied and/or unoccupied critical habitat. All areas that are designated as occupied habitat for a species are important for that species because these areas are either the last or one of the last remaining areas inhabited by the species and they meet the definition of critical habitat, making these areas necessary for maintaining the redundancy and representation for the species' conservation. This is the case for all sections and units, with the exception of *Schiedea hawaiiensis*—Section 19, which is critical habitat, but is not currently occupied habitat for any of the 12 species. We note which areas are the last remaining area known to be inhabited by a species.

We analyzed whether occupied areas were adequate for the conservation of each of the 12 species based on conservation goals within the recovery plan (Service 2022a, entire). We determined that occupied areas are not able to provide the space needed to meet the target number of reproductive populations and individuals for any of the 12 species. For four species with naturally narrowly-restricted ranges, no other areas containing their essential physical or biological features are known. We determined that for nine species (*Drosophila digressa, Cyanea marksii, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Schiedea hawaiiensis*) there are additional areas outside the geographical area occupied by the species that contain at least one physical or biological feature essential to the conservation of the species. We are designating as critical habitat all areas of unoccupied habitat that we identified for these nine species because (1) they provide one or more of the physical or biological features necessary for the reestablishment of wild populations within the species' range, and (2) we have reasonable certainty that these areas will contribute to the conservation of the species by adding to the area required to support the numbers of populations and reproducing individuals needed for recovery (thus helping to ensure resiliency, redundancy, and representation needed for the species' viability). The establishment of multiple, robust populations (redundancy) is a key component of conservation of these species (Service 2022a, pp. 29–30, 35, 39, 48–49). Due to the small numbers of individuals of each of these species, they require suitable habitat and space for expansion or introduction to achieve population levels that could approach recovery. Designating unoccupied areas as critical habitat for these species also supports recovery by allowing the habitat needed to establish additional populations able to withstand environmental stochasticity (resiliency) that otherwise has potential to eliminate a species from locations where it is currently found, and some species are only known from one location. Designating these unoccupied areas as critical habitat also promotes conservation actions to restore the species' historical, geographical, and ecological representation (representation), necessary for their recovery. For ease of reading and space efficiency, after first use of the full name of a plant section, we will refer to it by its section number only. For example, our first use of plant Section 2 is described as ''*Bidens hillebrandiana* ssp. *hillebrandiana*—Section 2,'' and after that is simply referred to as ''Section 2.''

TABLE 6—LAND USE, THREATS TO HABITAT, AND POTENTIAL SPECIAL MANAGEMENT CONSIDERATIONS FOR CRITICAL HABITAT UNITS DESIGNATED FOR THE 12 HAWAI'I ISLAND SPECIES

Plant section	Drosophila unit	General land use	Threats	Special management
Section 1	Unit 1	A, B, C, D, E, F, G	O, P, Q	S, T, U.
Section 2		A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 3		A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 4	Unit 7	A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 5	Unit 8	A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 6		A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 7		A, B, C, D, F, H	O, P, Q, R	S, T, U.
Section 8		A, E, F, G, H, I, J, K, L	O, P, Q	S, T.
Section 9		A, E, F, H, I, J	O, P, Q, R	S, T, U.
Section 10		A, B, C, D, E, F, G, H, M	O, P, Q, R	S, T, U.
Section 11	Unit 2	A, B, C, D, E, F, H, K, N	O, P, Q, R	S, T, U.
Section 12	Unit 9	A, B, C, D, F, H	O, P, Q, R	S, T, U.

TABLE 6—LAND USE, THREATS TO HABITAT, AND POTENTIAL SPECIAL MANAGEMENT CONSIDERATIONS FOR CRITICAL HABITAT UNITS DESIGNATED FOR THE 12 HAWAIʻI ISLAND SPECIES—Continued

Plant section	Drosophila unit	General land use	Threats	Special management
	Unit 4	A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 13	Unit 5	A, B, C, D, E, F, G, H	O, P, Q, R	S, T, U.
Section 14	Unit 3	A, E, F, H, I, J	O, P, Q, R	S, T, U.
Section 15		A, B, C, D, E, F, N	O, P, Q, R	S, T, U.
Section 16		A, B, C, D, E, F, N	O, P, Q, R	S, T, U.
Section 17		A, B, C, D, E, F, N	O, P, Q, R	S, T, U.
Section 18		A, B, C, D, E, F, N	O, P, Q, R	S, T, U.
Section 19		A, B, C, D, E, F, H	O, P, Q, R	S, T, U.
Section 20	Unit 6	A, B, C, D, E, F, J, N	O, P, Q, R	S, T.

Definition of Codes Used in Table 6

General land use:

A = Watershed protection
B = Ungulate and invasive plant control
C = Natural resource monitoring
D = Rare species protection and research
E = Public hunting
F = Public use and recreation
G = Education and outreach
H = Fire control
I = Natural resource conservation, including monitoring invasive plants and animals
J = Enhancement of native rare plant resources
K = Cultural uses
L = Personal gathering
M = Public use, including traditional and customary rights of Native Hawaiians
N = Timber management

Threats:

O = Habitat degradation due to rooting by feral ungulates
P = Intrusion of ecosystem-altering, invasive plants
Q = Changes in canopy cover due to plant disease
R = Fire

Special management considerations (see Special Management Considerations or Protection, in text above for additional detail):

S = Feral ungulate control
T = Measures to control spread of invasive plants
U = Fire management planning and wildfire response

Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 1 and Drosophila digressa—Unit 1

Section 1 and *Drosophila digressa*—Unit 1 consist of wet forest ecosystem from ʻŌʻōkala to Maulua Nui on the northeastern slope of Maunakea. Lands within this section and unit include approximately 26 percent in Federal ownership, 68 percent in State ownership, and 6 percent in private/other ownership (see table 3, above). Section 1 is comprised of two units: Unit 3 is a critical habitat unit within unit Hawaii 3 (see 50 CFR 17.99(k)), which was previously designated for other plant species; and Unit 52 is a newly designated critical habitat unit depicted on Map 119. All State-owned lands in this section and unit are managed by the State of Hawaii as part of the Hilo Forest Reserve Humuʻula, Laupāhoehoe, and Pīhā Sections; the Laupāhoehoe Natural Area Reserve; and the Manowaialeʻe Forest Reserve. All Federal lands in this section and unit are managed by the Service within Hakalau Forest National Wildlife Refuge, Hakalau Forest Unit. For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats identified within this section and unit, see table 6, above (DLNR–DOFAW 2022, entire; DLNR and USDA 2016, p. 4; Service 2010, pp. 1–13, 1–33–1–34; Stewart 2010, entire). The State lands within this section and unit are managed under the Laupāhoehoe Forest Management Plan (DLNR and USDA 2016, entire) and the Mauna Kea Watershed Management Plan (Stewart 2010, entire). The Federal lands within this section and unit are managed under the Hakalau Forest National Wildlife Refuge Comprehensive Conservation Plan (Service 2010, pp. 2–20–2–40) and the Mauna Kea Watershed Management Plan (Stewart 2010, entire).

Section 1 is occupied by the plants *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda,* and *Stenogyne cranwelliae.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Section 1 is important because it has the last remaining areas inhabited by *Cyrtandra wagneri* and *Melicope remyi,* and one of the last remaining areas inhabited by *Cyanea tritomantha, Phyllostegia floribunda,* and *Stenogyne cranwelliae,* making it an essential area for maintaining the redundancy and representation necessary for species' conservation. Although Section 1 is not known to be occupied by the plants *Pittosporum hawaiiense* and *Schiedea diffusa* ssp. *macraei,* and *Drosophila digressa*—Unit 1 is not known to be occupied by *Drosophila digressa,* this section and unit contain unoccupied habitat that is essential for the conservation of these species because they (1) are habitat for these species, (2) provide at least one of the physical or biological features essential for the conservation of each of these species, and (3) contribute to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, each plant species needs at least 10 populations, with at least 400 reproducing individuals per population for *Pittosporum hawaiiense* and 500 reproducing individuals per population for *Schiedea diffusa* ssp. *macraei* (Service 2022a, pp. 43–44). *Drosophila digressa* needs at least 10 stable populations for recovery (Service 2022a, p. 49). Therefore, we are reasonably certain that this section and unit will contribute to the conservation of these species and that this section and unit contain one or more of the physical or biological features that are essential to the conservation of these species. Approximately 12,059 ac (4,880 ha) of this section and unit overlap designated critical habitat for the federally endangered plants *Clermontia peleana, Cyanea platyphylla, Cyrtandra giffardii, Cyrtandra tintinnabula,* and *Phyllostegia warshaueri* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

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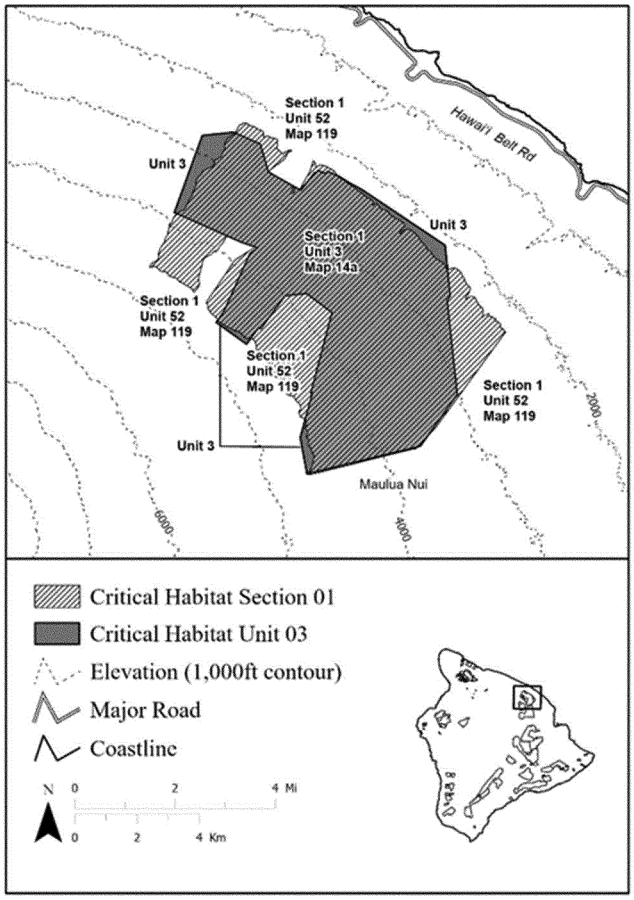
Figure 1. Area designated as critical habitat for *Cyanea tritomantha*, *Cyrtandra wagneri*, *Melicope remyi*, *Phyllostegia floribunda*, *Pittosporum hawaiiense*, *Schiedea diffusa* ssp. *macraei*, *Stenogyne cranwelliae* in Section 1. Section 1 consists of multiple critical habitat units: a portion of an existing critical habitat unit on Hawai'i Island (Unit 3) and the area designated as critical habitat on Hawai'i Island (Unit 52). Unit and map numbers for each section as published earlier (50 CFR 17.99(k)) are provided for ease of referencing.



Bidens hillebrandiana ssp. hillebrandiana—Section 2

Section 2 consists of coastal ecosystem from Pololū to Laupāhoehoe Iki on the northeastern slope of Kohala Mountain. Lands within this section include approximately 50 percent in State ownership and 50 percent in private/other ownership (see table 3, above). Section 2 is comprised of two units: Unit 6 is a critical habitat unit within unit Hawaii 6 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 53 is a newly designated critical habitat unit depicted on Map 120. All State-owned lands in Section 2 are managed by the State of Hawaii as part of the Pololū Section of the Kohala Forest Reserve and the Pu'u o 'Umi Natural Area Reserve. The State lands within this section are managed under the Pu'u o 'Umi Management Plan (DLNR–DOFAW 1989, entire) and Kohala Mountain Watershed Management Plan Draft (Kohala Watershed Partnership [KWP] 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats identified within this section, see table 6, above (DLNR–DOFAW 1989, entire; KWP 2007, entire).

Section 2 is occupied by the plant *Bidens hillebrandiana* ssp. *hillebrandiana* and includes the coastal habitat, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the coastal ecosystem. This section is especially important because it is the last remaining area inhabited by the species, which makes it an important area for maintaining the redundancy and representation necessary for species' conservation. Approximately 2 ac (1 ha) of this section overlap designated critical habitat for the federally endangered plant *Nothocestrum breviflorum* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 3

Section 3 consists of wet forest and wet grassland and shrubland ecosystems from Kahua to Pu'ukapu on Kohala Mountain. Lands within this section include approximately 99 percent in State ownership and 1 percent in private/other ownership (see table 3,

above). Section 3 is comprised of three units: Unit 8 and Unit 9 are critical habitat units within unit Hawaii 8 and unit Hawaii 9 (see 50 CFR 17.99(k)), which were previously designated for other plant species; and Unit 54 is a newly designated critical habitat unit depicted on Map 121. All State-owned lands in this section are managed by the State of Hawaii as part of the Kohala Forest Reserve, Kohala Watershed Forest Reserve, and Pu'u o 'Umi Natural Area Reserve. The State lands within this section are managed under the Pu'u o 'Umi Management Plan (DLNR–DOFAW 1989, entire) and the Kohala Mountain Watershed Management Plan Draft (KWP 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats identified within this section, see table 6, above (DLNR–DOFAW 1989, entire; KWP 2007, entire).

Section 3 is occupied by the plants *Cyanea tritomantha, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae,* and includes the wet forest and wet grassland and shrubland ecosystems, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest and wet grassland and shrubland ecosystems. Although Section 3 is not known to be occupied by *Melicope remyi* or *Phyllostegia floribunda,* this section contains unoccupied habitat that is essential for the conservation of these species because it (1) is habitat for these species, (2) provides at least one of the physical or biological features essential for the conservation of each of these species, and (3) contributes to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, each species needs at least 10 populations, with at least 200 reproducing individuals per population for *Melicope remyi* and at least 500 reproducing individuals per population for *Phyllostegia floribunda* (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of these species and that this section contains one or more of the physical or biological features that are essential to the conservation of these species. Approximately 6,941 ac (2,809 ha) of this section overlap designated critical habitat for the federally endangered plants *Clermontia drepanomorpha, Phyllostegia warshaueri,* and *Achyranthes mutica* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003); and for the picture-wing fly *Drosophila ochrobasis* Units 3 (Kohala Mountains East) and 4 (Kohala Mountains West) (see 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008).

Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 4 and Drosophila digressa—Unit 7

Section 4 and *Drosophila digressa*—Unit 7 consist of wet forest ecosystem from Kukuiopa'e to 'Ōlelomoana on the southwestern slopes of Mauna Loa. Lands within this section and unit include approximately 88 percent in State ownership and 12 percent in private/other ownership (see table 3, above). Section 4 is comprised of two units: Unit 15 is a critical habitat unit within unit Hawaii 15 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 39 is a newly designated critical habitat unit depicted on Map 108. All State-owned lands in this section and unit are managed by the State of Hawaii as part of the South Kona Forest Reserve Kukuiopa'e Section. The State lands within this section and unit are managed under the Three Mountain Alliance Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats identified within this section and unit, see table 6, above (TMA 2007, pp. 26–37; DLNR–DOFAW 2022, entire).

Section 4 is occupied by the plants *Cyanea marksii, Phyllostegia floribunda,* and *Pittosporum hawaiiense.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 4 is not known to be occupied by the plants *Schiedea diffusa* ssp. *macraei* and *Stenogyne cranwelliae,* and *Drosophila digressa*—Unit 7 is not known to be occupied by *Drosophila digressa,* this section and unit contain unoccupied habitat that is essential for the conservation of these species because they (1) are habitat for these species, (2) provide at least one of the physical or biological features essential for the conservation of each of these species, and (3) contribute to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Schiedea diffusa* ssp. *macraei* needs at least 10 populations, with at least 500 reproducing individuals per population, and *Stenogyne cranwelliae* needs at least 20 populations, with at least 500 reproducing individuals per population (Service 2022a, pp. 43–44). *Drosophila digressa* needs at least 10 stable populations for recovery (Service 2022a, p. 49). Therefore, we are reasonably certain that this section and unit will contribute to the conservation of these species and that this section and unit contain one or more of the physical or biological features that are essential to the conservation of these species. Approximately 182 ac (73 ha) of this section and unit overlap designated critical habitat for the federally endangered plant *Cyanea stictophylla* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

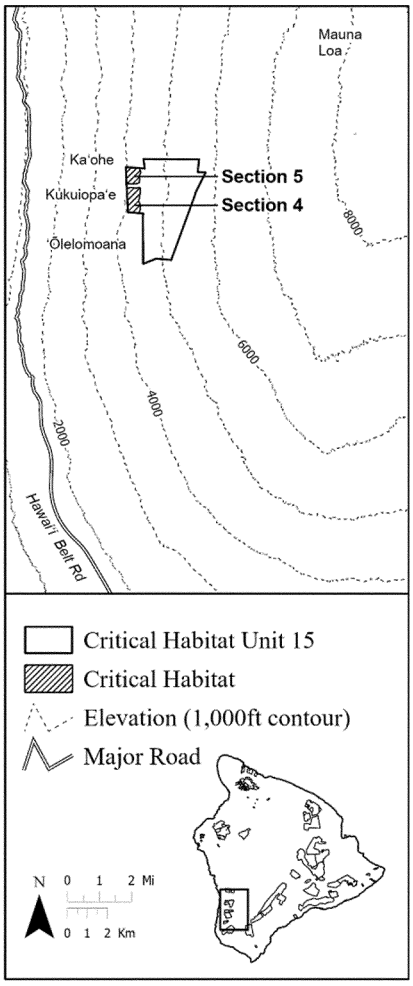


Figure 2. Area designated as critical habitat for *Cyanea marksii*, *Phyllostegia floribunda*, *Pittosporum hawaiiense*, *Schiedea diffusa* ssp. *macraei*, and *Stenogyne cranwelliae* in the portion of Section 4 within Unit 15 and in the portion of Section 5 within Unit 15. Sections 4 and 5 both overlay Unit 15, which is an existing critical habitat unit on Hawai‘i Island, but do not overlay each other.

Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 5 and Drosophila digressa—Unit 8

Section 5 and *Drosophila digressa*—Unit 8 consist of wet forest ecosystem in Kaʻohe on the southwestern slopes of Mauna Loa. Lands within this section and unit include approximately 53 percent in State ownership and 47 percent in private/other ownership (see table 3, above). Section 5 is comprised of two units: Unit 15 is a critical habitat unit within unit Hawaii 15 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 38 is a newly designated critical habitat unit depicted on Map 107. All State-owned lands in this section and unit are managed by the State of Hawaii as part of the South Kona Forest Reserve, Kaʻohe Section and Kukuiopaʻe Section. The State lands within this section and unit are managed under the Three Mountain Alliance Management Plan (TMA 2007, pp. 47–50). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats identified within this section and unit, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 26–37).

Section 5 is occupied by the plant *Cyanea marksii.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 5 is not known to be occupied by the plants *Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae,* and *Drosophila digressa*—Unit 8 is not known to be occupied by *Drosophila digressa,* this section and unit contain unoccupied habitat that is essential for the conservation of these species because they (1) are habitat for these species, (2) provide at least one of the physical or biological features essential for the conservation of each of these species, and (3) contribute to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Phyllostegia floribunda, Pittosporum hawaiiense,* and *Schiedea diffusa* ssp. *macraei* each need at least 10 populations, with at

least 500 reproducing individuals per population for *Phyllostegia floribunda* and *Schiedea diffusa* ssp. *macraei* and at least 400 reproducing individuals per population for *Pittosporum hawaiiense* (Service 2022a, pp. 43–44). For *Stenogyne cranwelliae,* at least 20 populations, each with at least 500 reproducing individuals, are necessary for recovery (Service 2022a, pp. 43–44). *Drosophila digressa* needs at least 10 stable populations for recovery (Service 2022a, p. 49). Therefore, we are reasonably certain that this section and unit will contribute to the conservation of these species and that this section and unit contain one or more of the physical or biological features that are essential to the conservation of these species. Approximately 127 ac (51 ha) of this section and unit overlap designated critical habitat for the federally endangered plant *Cyanea stictophylla* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 6

Section 6 consists of wet forest ecosystem in Kīpāhoehoe on the southwestern slopes of Mauna Loa. Lands within this section include approximately 96 percent in State ownership and 4 percent in private/other ownership (see table 3, above). Section 6 is comprised of two units: Unit 16 is a critical habitat unit within unit Hawaii 16 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 40 is a newly designated critical habitat unit depicted on Map 109. All State-owned lands in this section are managed by the State of Hawaii as part of the Kīpāhoehoe Natural Area Reserve. The State lands within this section are managed under the Kīpāhoehoe Natural Area Reserve Management Plan (DLNR–DOFAW 2002, entire) and the Three Mountain Alliance Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2002, entire).

Section 6 is occupied by the plants *Cyanea marksii* and *Phyllostegia floribunda.* This section includes the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 6 is not known to be occupied by *Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* or *Stenogyne cranwelliae,* this section contains unoccupied habitat that is essential for the conservation of these species because it (1) is habitat for these species, (2) provides at least one of the physical or biological features essential for the conservation of each of these species, and (3) contributes to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Pittosporum hawaiiense* and *Schiedea diffusa* ssp. *macraei* each need at least 10 populations, with at least 400 reproducing individuals per population for *Pittosporum hawaiiense* and at least 500 reproducing individuals per population for *Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of these species and that this section contains one or more of the physical or biological features that are essential to the conservation of these species. Approximately 156 ac (63 ha) of this section overlap designated critical habitat for the federally endangered plant *Cyanea stictophylla* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

Phyllostegia floribunda, Pittosporum hawaiiense—Section 7

Section 7 consists of wet forest and wet grassland and shrubland ecosystems from Pānau Nui to Kamoamoa on the eastern slope of Kīlauea Volcano, entirely on Federal land (see table 3, above). Section 7 is comprised of two units: Unit 23 is a critical habitat unit within unit Hawaii 23 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 45 is a newly designated critical habitat unit depicted on Map 114. Lands within this section are entirely under Federal ownership managed by the National Park Service within Hawai'i Volcanoes National Park. Federal lands within this section are managed by the National Park Service under the Hawai'i Volcanoes National Park General Management Plan (National Park Service 2015, 2016, entire) and the Three Mountain Alliance Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (National Park Service 2015, 2016, entire).

Section 7 is occupied by the plants *Phyllostegia floribunda* and *Pittosporum hawaiiense* and includes the wet forest and wet grassland and shrubland ecosystems, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest and wet grassland and shrubland ecosystems. Approximately 9 ac (4 ha) of this section overlap designated critical habitat for the federally endangered plant *Pleomele hawaiiensis* (now listed as *Dracaena konaensis*) (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

Cyanea tritomantha, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 8

Section 8 consists of wet and mesic forest ecosystems from Nīnole to Pāhala on the southern slopes of Mauna Loa. Lands within this section include approximately 29 percent in Federal ownership and 71 percent in State ownership (see table 3, above). Section 8 is comprised of two units: Unit 24 is a critical habitat unit within unit Hawaii 24 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 44 is a newly designated critical habitat unit depicted on Map 113. Federal lands in Section 8 are managed by the National Park Service within Hawai'i Volcanoes National Park and in accordance with the Hawai'i Volcanoes National Park General Management Plan (National Park Service 2015, 2016, entire). All State-owned lands in this section are managed by the State of Hawaii, are part of the Ka'ū Forest Reserve, and are managed under the Ka'ū Forest Reserve Management Plan (DLNR–DOFAW 2012, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within Section 8, see table 6, above (DLNR–DOFAW 2012, p. 3; TMA 2007, pp. 44–46).

Section 8 is occupied by the plants *Cyanea tritomantha, Pittosporum hawaiiense,* and *Schiedea diffusa* ssp. *macraei* and includes the wet and mesic forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet and mesic forest ecosystems. Although Section 8 is not known to be occupied by the plant *Stenogyne cranwelliae,* this section contains unoccupied habitat that is essential for the conservation of this species because it (1) is habitat for the species, (2) provides at least one of the physical or biological features essential for the conservation of the species, and (3) contributes to the area of habitat needed to reestablish wild populations

within their range in support of recovery criteria for the species. For recovery, *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of this species and that this section contains one or more of the physical or biological features that are essential to the conservation of the species. Approximately 2,081 ac (842 ha) of the section overlap designated critical habitat for the federally endangered plant *Argyroxiphium kauense* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003) and for the picture-wing fly *Drosophila heteroneura* Unit 1 (Kaʻū Forest) (see 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008).

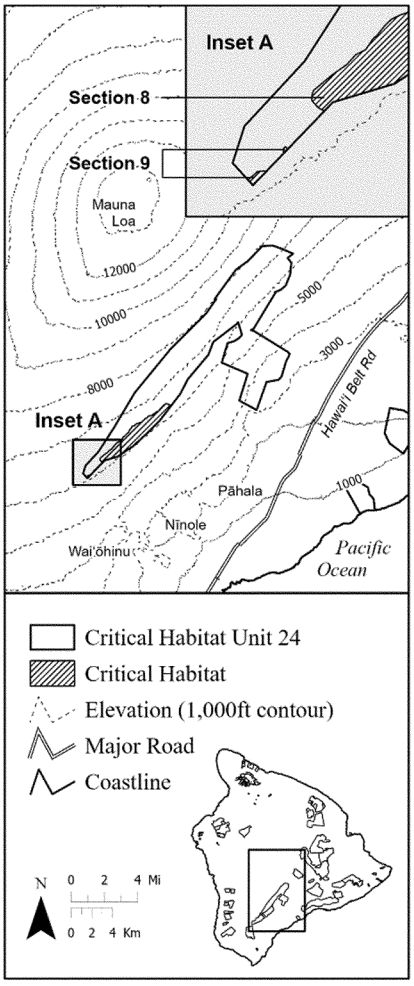


Figure 3. Area designated as critical habitat for *Cyanea tritomantha*, *Pittosporum hawaiiense*, *Schiedea diffusa* ssp. *macraei*, and *Stenogyne cranwelliae* in the portion of Section 8 within Unit 24 and for *Pittosporum hawaiiense*, *Schiedea diffusa* ssp. *macraei*, and *Stenogyne cranwelliae* in the portion of Section 9 within Unit 24. Sections 8 and 9 both overlay Unit 24, which is an existing critical habitat unit on Hawai‘i Island, but do not overlay each other.

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Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 9

Section 9 consists of wet and mesic forest ecosystems from Waiʻōhinu to Nīnole on the southern slopes of Mauna Loa. Lands within this section include approximately 29 percent in Federal ownership and 71 percent in State ownership (see table 3, above). Section 9 is comprised of two units: Unit 24 is a critical habitat unit within unit Hawaii 24 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 43 is a newly designated critical habitat unit depicted on Map 112. Federal lands in Section 9 are managed by the National Park Service within Hawai‘i Volcanoes National Park and in accordance with the Hawai‘i Volcanoes National Park General Management Plan (National Park Service 2015, 2016, entire). All State-owned lands in this section are managed by the State of Hawaii, are part of the Kaʻū Forest Reserve, and are managed under the Kaʻū Forest Reserve Management Plan (DLNR–DOFAW 2012, entire). For general land use, threats, and special management considerations or protection measures to

reduce or alleviate the threats within this section, see table 6, above (TMA 2007, pp. 26–37; DLNR–DOFAW 2012, pp. 1–3; DLNR 2017, pp. 3–5).

Section 9 is occupied by the plants *Pittosporum hawaiiense* and *Schiedea diffusa* ssp. *macraei* and includes the wet and mesic forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet and mesic forest ecosystems. Although Section 9 is not known to be occupied by *Stenogyne cranwelliae,* this section contains unoccupied habitat that is essential for the conservation of this species because it (1) is habitat for the species, (2) provides at least one of the physical or biological features essential for the conservation of the species, and (3) contributes to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for the species. For recovery, *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of this species and that this section contains one or more of the physical or biological features that are essential to the conservation of the species. Approximately 101 ac (41 ha) of this section overlap designated critical habitat for the federally endangered plant *Argyroxiphium kauense* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003) and for the picture-wing fly *Drosophila ochrobasis* Unit 5 (Upper Kahuku) (see 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008).

Cyrtandra nanawaleensis, Phyllostegia floribunda—Section 10

Section 10 consists of wet forest and wet grassland and shrubland ecosystems from Kahauale'a to Wao Kele o Puna near the east rift zone of Kīlauea Volcano in the district of Puna. Lands within this section include approximately 100 percent in State ownership and less than 1 percent in private/other ownership (see table 3, above). Section 10 is comprised of two units: Unit 28 is a critical habitat unit within unit Hawaii 28 (see 50 CFR 17.99(k)), which was previously designated for another plant species; and Unit 46 is a newly designated critical habitat unit depicted on Map 115. Lands within this section are almost entirely under State ownership managed by the State of Hawaii within the Kahauale'a Natural Area Reserve and the State of Hawaii Office of Hawaiian Affairs within the Wao Kele o Puna Forest Reserve. The State lands within this section are managed under the Wao Kele o Puna Comprehensive Management Plan (Nālehualawaku'ulei 2017, entire) and the Three Mountain Alliance Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 26–37; Nālehualawaku'ulei 2017, entire).

Section 10 is occupied by the plants *Cyrtandra nanawaleensis* and *Phyllostegia floribunda* and includes the wet forest and wet grassland and shrubland, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest and wet grassland and shrubland ecosystems. Approximately 155 ac (63 ha) of this section overlap designated critical habitat for the federally endangered plant *Adenophorus periens* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

Cyanea tritomantha, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 11 and Drosophila digressa—Unit 2

Section 11 and *Drosophila digressa*—Unit 2 consist of wet forest ecosystem from 'Ōla'a to Upper Waiākea on the eastern slope of Mauna Loa and partially on the northern slope of Kīlauea Volcano. Lands within this section and unit include approximately 25 percent in Federal ownership, 75 percent in State ownership, and less than 1 percent in private/other ownership (see table 3, above). Section 11 is comprised of three units: Unit 29 and Unit 30 are critical habitat units within unit Hawaii 29 and unit Hawaii 30 (see 50 CFR 17.99(k)), which were previously designated for other plant species; and Unit 51 is a newly designated critical habitat unit depicted on Map 118. All State-owned lands in this section and unit are managed by the State of Hawaii as part of the Hilo Forest Reserve Kūkūau Section, 'Ōla'a Forest Reserve Mountain View Section, Upper Waiākea Forest Reserve, Waiākea Forest Reserve, Pu'u Maka'ala Natural Area Reserve, and Waiākea 1942 Lava Flow Natural Area Reserve. All Federal lands in this section and unit are managed by the National Park Service within the Hawai'i Volcanoes National Park. The State lands within this section and unit are managed under the Pu'u Maka'ala Natural Area Reserve Management Plan (DLNR–DOFAW 2013, entire) and the Three Mountain Alliance's Management Plan (TMA 2007, entire). The Federal lands within this section and unit are managed under the Hawai'i Volcanoes National Park General Management Plan (National Park Service 2015, 2016, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section and unit, see table 6 (National Park Service 2015, 2016, entire; DLNR–DOFAW 2013, p. 21; DLNR–DOFAW 2022, entire; TMA 2007, pp. 40–43).

Section 11 is occupied by the plants *Cyanea tritomantha, Phyllostegia floribunda, Pittosporum hawaiiense,* and *Schiedea diffusa* ssp. *macraei,* and *Drosophila digressa*—Unit 2 is occupied by the picture-wing fly *Drosophila digressa.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 11 is not known to be occupied by *Stenogyne cranwelliae,* this section contains unoccupied habitat that is essential for the conservation of this species because it (1) is habitat for the species, (2) provides at least one of the physical or biological features essential for the conservation of the species, and (3) contributes to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for the species. For recovery, *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of this species and that this section contains one or more of the physical or biological features that are essential to the conservation of the species. Approximately 14,695 ac (5,947 ha) of this section and unit overlap designated critical habitat for the federally endangered plants *Clermontia peleana, Cyanea stictophylla, Cyrtandra giffardii, Phyllostegia velutina,* and *Sicyos alba* (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003), and for the picture-wing fly *Drosophila mulli* Unit 1 ('Ōla'a Forest) and Unit 3 (Waiākea Forest) (see 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008).

Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 12 and Drosophila digressa—Unit 9

Section 12 and *Drosophila digressa*—Unit 9 consist of wet forest ecosystem in Ho'okena on the southwestern slopes of Mauna Loa. Newly designated critical habitat for Section 12 is entirely within critical habitat Unit 37 depicted on Map

106 and includes approximately 100 percent Federal land with less than 1 ac (less than 1 ha) of land that is privately owned or has other ownership (see table 3, above). Lands within this section and unit are almost entirely managed by the Service within Hakalau Forest National Wildlife Refuge's Kona Forest Unit and in accordance with the Hakalau Forest National Wildlife Refuge Comprehensive Conservation Plan (Service 2010, pp. 2–13–2–19, 2–33–2–40). The State lands within this section and unit are managed under the Three Mountain Alliance Management Plan (TMA 2007, pp. 47–50). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section and unit, see table 6, above (Service 2010, entire; TMA 2007, pp. 26–37).

Section 12 is occupied by the plant *Cyanea marksii.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 12 is not known to be occupied by *Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* or *Stenogyne cranwelliae,* and *Drosophila digressa*—Unit 9 is not known to be occupied by *Drosophila digressa,* this section and unit contain unoccupied habitat that is essential for the conservation of these species because they (1) are habitat for these species, (2) provide at least one of the physical or biological features essential for the conservation of each of these species, and (3) contribute to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Phyllostegia floribunda* and *Schiedea diffusa* ssp. *macraei* each need at least 10 populations, with at least 500 reproducing individuals per population; *Pittosporum hawaiiense* needs at least 10 populations, each with at least 400 reproducing individuals; and *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). *Drosophila digressa* needs at least 10 stable populations for recovery (Service 2022a, p. 49). Therefore, we are reasonably certain that this section and unit will contribute to the conservation of these species and that this section and unit contain one or more of the physical or biological features that are essential to the conservation of these species. Approximately 1,482 ac (600 ha) of this section and unit overlap designated critical habitat for the picture-wing fly *Drosophila heteroneura* Unit 2 (Kona Refuge) (see 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008).

Drosophila digressa—Unit 4

Drosophila digressa—Unit 4 consists of mesic forest ecosystem at Manukā on the southern slopes of Mauna Loa, with 100 percent of lands in State ownership (see table 3, above). All State-owned lands in this unit are managed by the State of Hawaii as part of the Manukā Natural Area Reserve, under the Manukā Natural Area Reserve Draft Management Plan (DLNR–DOFAW 1992, entire) and the Three Mountain Alliance Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this unit, see table 6, above (DLNR–DOFAW 1992, entire).

Drosophila digressa—Unit 4 is occupied by the picture-wing fly *Drosophila digressa* and includes the mesic forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the mesic forest ecosystem. This entire unit (167 ac, 67 ha) overlaps designated critical habitat for the federally endangered plants *Colubrina oppositifolia, Diellia erecta* (now listed as *Asplenium dielerectum*), *Flueggea neowawraea, Gouania vitifolia, Neraudia ovata,* and *Pleomele hawaiiensis* (now listed as *Dracaena konaensis*) (see 50 CFR 17.99(k) and 68 FR 39624, July 2, 2003).

Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 13 and Drosophila digressa—Unit 5

Section 13 and *Drosophila digressa*—Unit 5 consist of wet forest ecosystem from Kīpāhoehoe to Honomalino on the southwestern slopes of Mauna Loa. Lands within this section and unit include approximately 12 percent in State ownership and 88 percent in private/other ownership (see table 3, above). Newly designated critical habitat for Section 13 is entirely within critical habitat Unit 41 depicted on Map 110. All State-owned lands in this section and unit are managed by the State of Hawaii as part of the Kīpāhoehoe Natural Area Reserve and South Kona Forest Reserve Kapua-Manukā Section. Some private lands are owned by The Nature Conservancy, within the Kona Hema Preserve. The State lands within this section and unit are managed under the Kīpāhoehoe Natural Area Reserve Management Plan (DLNR–DOFAW 2002, entire) and the Three Mountain Alliance Management Plan (TMA 2007, entire). The Nature Conservancy's land is managed under the Forest Stewardship Management Plan for the Kona Hema Preserve (The Nature Conservancy 2017, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section and unit, see table 6, above (DLNR–DOFAW 2002, entire).

Section 13 is occupied by the plants *Cyanea marksii, Phyllostegia floribunda,* and *Pittosporum hawaiiense.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 13 is not known to be occupied by *Schiedea diffusa* ssp. *macraei* and *Stenogyne cranwelliae,* and *Drosophila digressa*—Unit 5 is not known to be occupied by *Drosophila digressa,* this section and unit contains unoccupied habitat that is essential for the conservation of these species because they (1) are habitat for these species, (2) provide at least one of the physical or biological features essential for the conservation of each of these species, and (3) contribute to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Schiedea diffusa* ssp. *macraei* needs at least 10 populations, each with at least 500 reproducing individuals, and *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). *Drosophila digressa* needs at least 10 stable populations for recovery (Service 2022a, p. 49). Therefore, we are reasonably certain that this section and unit will contribute to the conservation of these species and that this section and unit contain one or more of the physical or biological features that are essential to the conservation of these species. There is no designated critical habitat for other listed species within this section and unit.

Cyanea tritomantha, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa ssp. macraei, Stenogyne cranwelliae—Section 14 and Drosophila digressa—Unit 3

Section 14 and *Drosophila digressa*—Unit 3 are entirely overlapping and consist of wet and mesic forest ecosystems at Kahuku on the southern

slopes of Mauna Loa. Newly designated critical habitat for Section 14 is comprised of a single unit of newly designated critical habitat, Unit 42 depicted on Map 111. Lands within this section and unit include approximately 100 percent in Federal ownership and less than 1 percent in State ownership (see table 3, above). Federal lands are managed by the National Park Service within the Hawai'i Volcanoes National Park in accordance with the Hawai'i Volcanoes National Park General Management Plan (National Park Service 2015, 2016, entire). All State-owned lands in this section and unit are managed by the State of Hawaii, are part of the Ka'ū Forest Reserve, and are managed under the Ka'ū Forest Reserve Management Plan (DLNR–DOFAW 2012, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section and unit, see table 6, above (TMA 2007, pp. 26–37; DLNR–DOFAW 2012, pp. 1–3; DLNR 2017, pp. 3–5).

Section 14 is occupied by the plants *Pittosporum hawaiiense* and *Schiedea diffusa* ssp. *macraei.* This section and unit include the wet and mesic forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet and mesic forest ecosystems. Although Section 14 is not known to be occupied by the plants *Cyanea tritomantha, Phyllostegia floribunda,* or *Stenogyne cranwelliae,* or by the picture-wing fly *Drosophila digressa* in *Drosophila digressa*—Unit 3, this section and unit contain unoccupied habitat that is essential for the conservation of these species because they (1) are habitat for these species, (2) provide at least one of the physical or biological features essential for the conservation of each of these species, and (3) contribute to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Cyanea tritomantha* and *Phyllostegia floribunda* each need at least 10 populations, with at least 500 reproducing individuals per population, and *Stenogyne cranwelliae* needs at least 20 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). *Drosophila digressa* needs at least 10 stable populations for recovery (Service 2022a, p. 49). Therefore, we are reasonably certain that this section and unit will contribute to the conservation of these species and that this section and unit contain one or more of the physical or biological features that are essential to the conservation of these species. Approximately 681 ac (275 ha) of this section and unit overlap designated critical habitat for the picture-wing fly *Drosophila heteroneura* Unit 3 (Lower Kahuku) (see 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008).

Cyrtandra nanawaleensis—Section 15

Section 15 consists of wet forest ecosystem at Kamā'ili near the east rift zone of Kīlauea Volcano in the district of Puna. Lands within this section are entirely under State ownership managed by the State of Hawaii within the Keau'ohana Forest Reserve (see table 3, above). Section 15 is comprised of one unit: Unit 47, which is a newly designated critical habitat unit depicted on Map 116. The State lands within this section are managed under the Three Mountain Alliance's Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 40–43).

Section 15 is occupied by the plant *Cyrtandra nanawaleensis* and includes the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. There is no designated critical habitat for other listed species within the section.

Cyrtandra nanawaleensis—Section 16

Section 16 consists of wet forest ecosystem in Pāhoa near the east rift zone of Kīlauea Volcano in the district of Puna. Lands within this section include approximately 99 percent under State ownership and 1 percent in private/other ownership (see table 3, above). Section 16 is comprised of one unit: Unit 48, which is a newly designated critical habitat unit depicted on Map 116. All State-owned lands in this section are managed by the State of Hawaii as part of the Nānāwale Forest Reserve, under the Three Mountain Alliance's Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 40–43).

Section 16 is occupied by the plant *Cyrtandra nanawaleensis* and includes the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. There is no designated critical habitat for other listed species within the section.

Cyrtandra nanawaleensis—Section 17

Section 17 consists of wet and mesic forest and mesic grassland and shrubland ecosystems at Malama-Kī near the east rift zone of Kīlauea Volcano in the district of Puna. Lands within this section include approximately 99 percent under State ownership and 1 percent in private/other ownership (see table 3, above). Section 17 is comprised of one unit: Unit 49, which is a newly designated critical habitat unit depicted on Map 117. State-owned lands within this section are managed by the State of Hawaii within the Malama-Kī Forest Reserve, under the Three Mountain Alliance's Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 40–43).

Section 17 is occupied by the plant *Cyrtandra nanawaleensis* and includes the wet forest, mesic forest, and mesic grassland and shrubland; the moisture regime; and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest, mesic forest, and mesic grassland and shrubland ecosystems. There is no designated critical habitat for other listed species within the section.

Cyrtandra nanawaleensis—Section 18

Section 18 consists of wet and mesic forest and mesic grassland and shrubland ecosystems at Kapoho near the east rift zone of Kīlauea Volcano in the district of Puna. Lands within this section are entirely under State ownership (see table 3, above). Section 18 is comprised of one unit: Unit 50, which is a newly designated critical habitat unit depicted on Map 117. State-owned lands within this section are managed by the State of Hawaii within the Nānāwale Forest Reserve Halepua'a section, under the Three Mountain Alliance's Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 40–43).

Section 18 is occupied by the plant *Cyrtandra nanawaleensis* and includes the wet forest, mesic forest, and mesic grassland and shrubland; the moisture regime; and canopy, subcanopy, and

understory native plant species identified as the physical or biological features in the wet forest, mesic forest, and mesic grassland and shrubland ecosystems. There is no designated critical habitat for other listed species within the section.

Schiedea hawaiiensis—Section 19

Section 19 consists of dry forest ecosystem adjacent to the Pōhakuloa Training Area in the saddle of Maunakea, Mauna Loa, and Hualālai. Lands within this section are entirely in State ownership (see table 3, above). Designated critical habitat for Section 19 is entirely within critical habitat Unit 55 depicted on Map 122. The State-owned lands in this section include the Puʻu Anahulu Game Management Area and are managed under the Three Mountain Alliance Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section, see table 6, above (DLNR–DOFAW 2015, entire; TMA 2007, pp. 51–55).

Section 19 is not known to be occupied by *Schiedea hawaiiensis,* but this section includes the dry forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the dry forest ecosystems. This section also provides an area for potential population establishment, which is essential for the conservation of *Schiedea hawaiiensis* because 10 populations are identified as part of the recovery criteria, but only 1 wild population and 3 reintroduced populations are extant. Although Section 19 contains unoccupied habitat for *Schiedea hawaiiensis,* we have determined this area is essential for the conservation of this species because it (1) is habitat for this species, (2) provides at least one of the physical or biological features essential for the conservation of this species, and (3) contributes to the area of habitat needed to reestablish wild populations within their range in support of the species' recovery criteria. At least 10 populations, each with at least 500 reproducing individuals, are necessary for the species' recovery (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of this species and that this section contains one or more of the physical or biological features that are essential to the conservation of this species. Section 19 does not overlap with existing critical habitat for other listed species.

Cyanea marksii, Schiedea diffusa ssp. macraei—Section 20 and Drosophila digressa—Unit 6

Section 20 and *Drosophila digressa*—Unit 6 consist of wet forest ecosystem from Miloliʻi to Honomalino on the southwestern slopes of Mauna Loa. Lands within this section and unit are entirely in State ownership (see table 3, above). Newly designated critical habitat for Section 20 is entirely within critical habitat Unit 56 depicted on Map 123. All State-owned lands in this section and unit are managed by the State of Hawaii as part of the South Kona Forest Reserve Kapua-Manukā Section, under the Three Mountain Alliance's Management Plan (TMA 2007, entire). For general land use, threats, and special management considerations or protection measures to reduce or alleviate the threats within this section and unit, see table 6, above (DLNR–DOFAW 2022, entire; TMA 2007, pp. 47–50).

Drosophila digressa—Unit 6 is occupied by the picture-wing fly *Drosophila digressa.* This section and unit include the wet forest, the moisture regime, and canopy, subcanopy, and understory native plant species identified as the physical or biological features in the wet forest ecosystem. Although Section 20 is not known to be occupied by *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei,* this section contains unoccupied habitat that is essential for the conservation of these species because it (1) is habitat for these species, (2) provides at least one of the physical or biological features essential for the conservation of each of these species, and (3) contributes to the area of habitat needed to reestablish wild populations within their range in support of recovery criteria for each of these species. For recovery, *Cyanea marksii* and *Schiedea diffusa* ssp. *macraei* each need at least 10 populations, each with at least 500 reproducing individuals (Service 2022a, pp. 43–44). Therefore, we are reasonably certain that this section will contribute to the conservation of these species and that this section contains one or more of the physical or biological features that are essential to the conservation of these species. There is no critical habitat for other endangered or threatened species within this section and unit.

Effects of Critical Habitat Designation

Section 7 Consultation

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

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

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

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

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

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

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

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

(3) Are economically and technologically feasible, and

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

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

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate consultation if any of the following four conditions occur: (1) the amount or extent of taking specified in the incidental take statement is exceeded; (2) new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) the identified action is

subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or (4) a new species is listed or critical habitat designated that may be affected by the identified action. The reinitiation requirement applies only to actions that remain subject to some discretionary Federal involvement or control. As provided in 50 CFR 402.16, the requirement to reinitiate consultations for new species listings or critical habitat designation does not apply to certain agency actions (*e.g.,* land management plans issued by the Bureau of Land Management in certain circumstances).

Destruction or Adverse Modification of Critical Habitat

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

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

Activities that we may, during a consultation under section 7(a)(2) of the Act, consider likely to destroy or adversely modify the critical habitat designated in this final rule include, but are not limited to, Federal actions that result in the removal or significant modification of designated critical habitat, or that would pose a risk of fire. Such activities may include military training activities with potential to cause wildland fires. We anticipate that most Federal activities that may cause effects to the critical habitat we are designating in this rule will also cause effects to the listed species, and as such we will already be in consultation with the Federal agency as to whether or not the activity jeopardizes the listed species. The exception is Section 19 (Unit 55), which we are designating as critical habitat for *Schiedea hawaiiensis* but that section is not occupied by any of the 12 species addressed in this rulemaking. As there is not already a section 7 consultation nexus based solely on the effects to these species (in the absence of them in the area presently), the effects of a Federal proposed action that could remove the physical or biological features essential to the conservation of the species—specifically, the associated native plant genera that are part of a functioning ecosystem in which *S. hawaiiensis* occurs or has historically occurred—would trigger section 7(a)(2) consultation because of the critical habitat designation. Within occupied areas, we do not anticipate recommending any project modifications to avoid destruction or adverse modification of critical habitat that would be different from those for avoiding jeopardy.

Exemptions

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

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an INRMP prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

We consult with the military on the development and implementation of INRMPs for installations with listed species. *Schiedea hawaiiensis* is the only species with a completed, Service-approved INRMP for DoD lands located within the range of its critical habitat designation, as described below.

Approved INRMPs

Pōhakuloa Training Area, 132,193 ac (53,497 ha)

The Pōhakuloa Training Area (PTA) is the sole installation under DoD jurisdiction on the island of Hawai'i. The PTA is located in the north-central portion on the island of Hawai'i, west of the Humu'ula Saddle, in an area formed by the convergence of three volcanic mountains: Mauna Kea, Mauna Loa, and Hualālai. The PTA INRMP provides for wildlife management and habitat enhancement for four federally listed animal species and 20 federally listed plant species, including *Schiedea hawaiiensis,* found within the PTA (PTA 2020, entire).

The current PTA INRMP provides specific protections for *S. hawaiiensis.* Conservation actions to benefit *S. hawaiiensis* include collection and storage of seed from both wild and cultivated plants, propagation of plants from seed that are planted into suitable off-site habitat, and quarterly monitoring of plants to gauge the efficacy of management actions. All known wild *S. hawaiiensis* individuals are protected in fenced enclosures and are monitored at least annually. Seeds from wild and propagated *S. hawaiiensis* plants have been collected and stored, and hundreds of propagated *S. hawaiiensis* individuals have been outplanted at the PTA and in protected, off-site native habitats. With partnering agencies, the DoD constructed 15 fenced units encompassing all known wild individuals of *S. hawaiiensis* in addition to other high-priority species in the PTA. Combined, these units protect roughly 37,300 ac (15,095 ha) of predominantly native forest from ungulates. The DoD also controls invasive plants and rodents within these fenced areas. The INRMP incorporates recommendations made by the Service to reduce fire risk. For example, wildland fires caused by military training activities are minimized by managing vegetation along a system of

fuel breaks and by controlling invasive grasses, which function as fine fuels, in buffers around occurrences of *S. hawaiiensis* and other listed species.

Based on the above considerations, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that the identified lands are subject to the PTA INRMP and that conservation efforts identified in the INRMP will provide a benefit to *S. hawaiiensis.* Therefore, lands within this installation are exempt from critical habitat designation under section 4(a)(3) of the Act. As such, and as we indicated in our March 29, 2023, proposed rule (88 FR 18756), we are not including approximately 22,730 ac (9,198 ha) of habitat in this final critical habitat designation because of this exemption.

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

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. Exclusion decisions are governed by the regulations at 50 CFR 424.19 and the Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act (hereafter, the ''2016 Policy''; 81 FR 7226, February 11, 2016)—both of which were developed jointly with the National Marine Fisheries Service (NMFS). We also refer to a 2008 Department of the Interior Solicitor's opinion entitled, ''The Secretary's Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act'' (M–37016). We explain each decision to exclude areas, as well as decisions not to exclude, to demonstrate that the decision is reasonable.

The Secretary may exclude any particular area if she determines that the benefits of such exclusion outweigh the benefits of including such area as part of the critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

We describe below the process that we undertook for deciding whether to exclude any areas—taking into consideration each category of impacts and our analysis of the relevant impacts.

Exclusions Based on Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. In order to consider economic impacts, we prepared an incremental effects memorandum (IEM) and screening analysis which, together with our narrative and interpretation of effects, we consider our economic analysis of the critical habitat designation and related factors (Service 2023o, entire; Industrial Economics, Incorporated (IEc) 2023a, entire). The economic analysis addressed probable economic impacts of critical habitat designation for the 12 Hawai'i species. Following the close of the comment period, we reviewed and evaluated all information submitted during the comment period that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Additional information relevant to the economic analysis of the critical habitat designation for the 12 Hawai'i species is summarized below and available in the screening analysis for the 12 Hawai'i species (IEc 2023a, entire), available at *https://www.regulations.gov.*

In our economic screening analysis (IEc, 2023a, entire), we identified probable incremental economic impacts associated with the critical habitat designation of the 12 Hawai'i Island species that have a Federal nexus (Service 2023o, entire). Because we are designating as critical habitat one area (*Cyanea marksii, Schiedea diffusa* ssp. *macraei*—Section 20 and *Drosophila digressa*—Unit 6) in this final rule that is in addition to the designation we originally proposed, we considered the economic impacts of the addition in our final economic screening analysis and concluded that the total incremental costs of this final critical habitat designation are not expected to change relative to those projected for our proposed designation (IEc 2023b, p. 1).

Critical habitat designation generally will not affect activities that do not have any Federal involvement. Under section 7 of the Act, Federal agencies are required to consult with the Service on activities they fund, permit, or implement that may affect the species or its critical habitat. When this final rule is effective (see **DATES**, above), Federal agencies will be required to consider the effects of their actions on the designated critical habitat of the 12 Hawai'i Island species. If the Federal action may affect critical habitat, our consultations will include measures to avoid the destruction or adverse modification of critical habitat.

In our IEM, we distinguished between the economic effects that result from the species being listed versus those attributable to the critical habitat designation. The following specific circumstances in this case help to inform our evaluation: (1) the essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species; and (2) any actions that would likely adversely affect the essential physical or biological features of critical habitat are also likely to adversely affect any one of the 12 Hawai'i Island species, if present. In general, most of the economic effects result from the listing of the species in the first instance, rather than resulting from the designation of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts resulting from the listing of the species and the incremental impacts of the designation of critical habitat for these species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this designation of critical habitat.

The critical habitat designation for the 12 Hawai'i Island species includes 21 distinct areas, subdivided into 42 units, totaling approximately 119,326 ac (48,289 ha). Lands within the designation are under Federal (27 percent), State (69 percent) and private/other (4 percent) ownership. All units except one were occupied by one or more of the 12 species at the time of listing. The single unoccupied unit (*Schiedea hawaiiensis*—Section 19) is not located in the PTA, and any incremental costs to minimize wildfire risk to Section 19 (Unit 55) because of military training is dependent upon the U.S. Army's proposed action to be described in their upcoming biological assessment. Overall, the incremental costs of designating critical habitat for the 12 Hawai'i Island species are likely to be limited to additional administrative effort to the consulting Federal agencies in conducting the adverse modification analysis. This additional administrative effort will be part of those section 7 consultations already required because of the Federal action's effects to listed species.

The additional administrative effort associated with considering critical

habitat during the section 7 consultation process was estimated using data regarding level of effort needed in past consultations, including efforts to provide technical assistance to Federal agencies short of requiring consultation, as well as efforts involving informal and formal consultation. We estimate up to six requests for technical assistance, one informal consultation, and two formal consultations annually over the next 10 years. The maximum annual cost associated with these consultations is estimated not to exceed $48,000 (2022 dollars). Therefore, the annual administrative burden is not expected to exceed the $200 million per year threshold that is considered economically significant under Executive Order (E.O.) 12866, as amended by E.O. 14094.

We anticipate that in general this critical habitat designation is not likely to add to our recommendations for project modifications during future section 7 consultations, as any such recommendations would likely be as a result of considering effects to the species in the first place. However, in some instances, we may recommend modifications associated specifically with minimizing adverse effects to the designated critical habitat in order to ensure the Federal activities will not result in the destruction or adverse modification of critical habitat.

For example, for activities with a Federal nexus that would involve entry into critical habitat that is susceptible to rapid ʻōhiʻa death (ROD), we anticipate recommending disinfecting gear to limit the transmission of fungal pathogens associated with ROD, and limiting trampling or damage to ʻōhiʻa in native-dominated forest areas. Disinfecting and other ROD control protocols are already part of best practices promoted by the Service and widely adopted by other agencies and conservation organizations. Therefore, such recommendations are unlikely to result in incremental costs because they are already part of standard protocols absent critical habitat.

In unpredictable cases, a Federal agency may need to act to save human lives in response to volcanic activity or other such emergencies involving acts of God, disasters, casualties, national defense or security emergencies. In doing so this may result in effects to listed species and critical habitat. We expect the Federal agency would use the emergency consultation procedures available, including obtaining technical advice and recommendations from the Service for minimizing adverse effects during emergency response activities whenever possible, and subsequently consulting with the Service (see 50 CFR 402.05). We may determine that the emergency response may adversely modify critical habitat and recommend restoration activities to address the damage to habitat that would not be undertaken absent a critical habitat designation. If time allows, the Service may also be involved in designing the emergency response in order to minimize the potential for adverse effects on critical habitat, for example, for emergency access road placement. Data are not available to forecast costs associated with modifications to activities or restoration actions following emergency response efforts during volcanic activity or other unpredictable events. Even if historical costs were available, the incremental costs associated with any given emergency response activity are likely to vary widely and be highly fact- and context-specific.

The probable incremental economic impacts of the critical habitat designations for the 12 Hawaiʻi Island species are expected to be limited to additional administrative effort as well as minor costs of conservation efforts resulting from a small number of future section 7 consultations. This limited incremental economic impact is due to a large portion (94 percent) of the critical habitat designation being occupied by one or more of the 12 Hawaiʻi Island species and thus would require consultation for the species anyway (regardless of critical habitat), making additional incremental economic impacts of critical habitat designation limited mostly to administrative costs. At approximately $30,000 or less per consultation, the burden resulting from the designation of critical habitat for the 12 Hawaiʻi Island species, based on the anticipated annual number of consultations and associated consultation costs, is not expected to exceed a total of $48,000 in most years, across all affected parties, including the Service and other Federal agencies, and any other involved party. These costs incorporate requests for technical assistance and informal and formal consultation. We are not aware of any State or local regulations that would add additional requirements to private activities as a result of the Federal designation of critical habitat. Thus, the annual administrative burden is low.

Although we do not anticipate incremental costs outside of the section 7 consultation process, additional incremental costs may occur if landowners or buyers perceive that the designation of critical habitat will restrict land or water use activities in some way and, therefore, lower the value or use of the land. Although we acknowledge the potential for these types of speculation-based costs, the likelihood of these potential future effects is uncertain, and data with which to estimate incremental costs are unavailable. Similarly, there may be economic impacts associated with the perceived beneficial effects of critical habitat on land values. However, the likelihood and magnitude of those such effects are also uncertain.

In summary, while the specific costs of critical habitat designation for the 12 Hawaiʻi Island species are subject to uncertainty, it is unlikely that this rule will generate costs exceeding $200 million in a single year. Therefore, this rule is unlikely to meet the threshold for an economically significant rule, with regard to costs, under E.O. 12866, as amended by E.O. 14094.

As discussed above, we considered the economic impacts of the critical habitat designation, and the Secretary is not exercising her discretion to exclude any areas from this designation of critical habitat for the 12 Hawaiʻi species based on economic impacts.

Exclusions Based on Impacts on National Security and Homeland Security

In preparing this rule, we determined that there are no lands within the designated critical habitat for the 12 Hawaiʻi species that are owned or managed by the DoD or Department of Homeland Security, and, therefore, we anticipate no impact on national security or homeland security. We did not receive any additional information during the public comment period for the proposed designation regarding impacts of the designation on national security or homeland security that would support excluding any specific areas from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19, as well as the 2016 Policy.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are permitted conservation plans covering the species in the area such as HCPs, safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs), or whether there are non-permitted conservation

agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at whether Native Hawaiian Community conservation plans or partnerships, Native Hawaiian Organization resources, or government-to-government relationships of the United States with indigenous entities may be affected by the designation. We also consider any State, local, social, or other impacts that might occur because of the designation.

When identifying the benefits of inclusion for an area, we consider the additional regulatory benefits that area would receive due to the protection from destruction or adverse modification as a result of actions with a Federal nexus, the educational benefits of mapping essential habitat for recovery of the listed species, and any benefits that may result from a designation due to State or Federal laws that may apply to critical habitat. In the case of the 12 Hawai'i species, the benefits of critical habitat include public awareness of the presence of these species and the importance of habitat protection, and, where a Federal nexus exists, increased habitat protection for these species due to the requirement to consult with the Service to avoid destroying or adversely modifying critical habitat.

When identifying the benefits of exclusion, we consider, among other things, whether exclusion of a specific area is likely to result in conservation, or in the continuation, strengthening, or encouragement of partnerships. Additionally, continued implementation of an ongoing management plan that provides equal to or more conservation than a critical habitat designation would reduce the benefits of including that specific area in the critical habitat designation.

We evaluate the existence of a conservation plan when considering the benefits of inclusion. We consider a variety of factors, including, but not limited to, whether the plan is finalized; how it provides for the conservation of the essential physical or biological features; whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan will be implemented into the future; whether the conservation strategies in the plan are likely to be effective; and whether the plan contains a monitoring program or adaptive management to ensure that the conservation measures are effective and can be adapted in the future in response to new information.

After identifying the benefits of inclusion and the benefits of exclusion, we carefully weigh the two sides to evaluate whether the benefits of exclusion outweigh those of inclusion. If our analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, we then determine whether exclusion would result in extinction of the species. If exclusion of an area from critical habitat will result in extinction, we will not exclude it from the designation.

We evaluated whether certain lands in the proposed critical habitat designation are appropriate for exclusion from this final designation under section 4(b)(2) of the Act. In our March 29, 2023, proposed rule (88 FR 18756), we identified the areas we were considering for exclusion based largely on their conservation management; we received no additional requests from entities seeking additional exclusions in comments on the proposed rule. If the analysis indicates that the benefits of excluding lands from this final designation outweigh the benefits of designating those lands as critical habitat, then the Secretary may exercise her discretion to exclude those lands from the final designation. In the paragraphs below, we provide our analysis of the areas being excluded from this designation under section 4(b)(2) of the Act.

Private or Other Non-Federal Conservation Plans or Agreements and Partnerships, in General

We sometimes exclude specific areas from critical habitat designations based in part on the existence of private or other non-Federal conservation plans or agreements and their attendant partnerships. A conservation plan or agreement describes actions that are designed to provide for the conservation needs of a species and its habitat and may include actions to reduce or mitigate negative effects on the species caused by activities on or adjacent to the area covered by the plan. Conservation plans or agreements can be developed by private entities with no Service involvement or in partnership with the Service.

We evaluate a variety of factors to determine how the benefits of any exclusion and the benefits of inclusion are affected by the existence of private or other non-Federal conservation plans or agreements and their attendant partnerships when we undertake a discretionary section 4(b)(2) exclusion analysis. A non-exhaustive list of factors that we will consider for non-permitted plans or agreements is shown below. These factors are not required elements of plans or agreements, and all items may not apply to every plan or agreement.

a. The degree to which the record of the plan supports a conclusion that a critical habitat designation would impair the realization of benefits expected from the plan, agreement, or partnership.

b. The extent of public participation in the development of the conservation plan.

c. The degree to which there has been agency review and required determinations (*e.g.,* State regulatory requirements), as necessary and appropriate.

d. Whether National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) compliance was required.

e. The demonstrated implementation and success of the chosen mechanism.

f. The degree to which the plan or agreement provides for the conservation of the essential physical or biological features for the species.

g. Whether there is a reasonable expectation that the conservation management strategies and actions contained in the conservation plan or agreement will be implemented.

h. Whether the plan or agreement contains a monitoring program and adaptive management to ensure that the conservation measures are effective and can be modified in the future in response to new information.

Watershed Partnerships—One factor we considered in our exclusion analysis is whether the landowner participates in a watershed partnership. In 2003, the State of Hawaii formally established the Hawai'i Association of Watershed Partnerships, which consists of more than 60 public and private landowners throughout the State; these landowners are committed to long-term protection and conservation of watershed areas. These watershed partnerships each have a conservation management plan that is updated every several years to include measurable objectives and a budget. Financial support for the watershed partnerships includes various long-term State funds and other Federal and private sources. Of the 10 watershed partnerships in operation, 3 have lands within the critical habitat designation: Mauna Kea Watershed Alliance, Kohala Watershed Alliance, and Three Mountain Alliance. These watershed partnerships fund and conduct conservation efforts, including ungulate control and removal, and invasive weed management, that support one or more of the 12 Hawai'i Island species. The specific management plan associated with each watershed alliance or partnership is described in ''Non-

Permitted Conservation Plans, Agreements, or Partnerships,'' below.

Private or Other Non-Federal Conservation Plans Related to Permits Under Section 10 of the Act

HCPs for incidental take permits under section 10(a)(1)(B) of the Act provide for partnerships with non-Federal entities to minimize and mitigate impacts to listed species and their habitat. In some cases, HCP permittees agree to do more for the conservation of the species and their habitats on private lands than designation of critical habitat would provide alone. We place great value on the partnerships that are developed during the preparation and implementation of HCPs.

CCAAs and SHAs are voluntary agreements designed to conserve candidate and listed species, respectively, on non-Federal lands. In exchange for actions that contribute to the conservation of species on non-Federal lands, participating property owners are covered by an ''enhancement of survival'' permit under section 10(a)(1)(A) of the Act, which authorizes incidental take of the covered species that may result from implementation of conservation actions, specific land uses, and, in the case of SHAs, the option to return to a baseline condition under the agreements. We also provide enrollees assurances that we will not impose further land-, water-, or resource-use restrictions, or require additional commitments of land, water, or finances, beyond those agreed to in the agreements.

When we undertake a discretionary section 4(b)(2) exclusion analysis, we will always consider areas covered by an approved CCAA/SHA/HCP, and we anticipate consistently excluding such areas if incidental take caused by the activities in those areas is covered by the permit under section 10 of the Act and the CCAA/SHA/HCP meets *all* of the following three factors (see the 2016 Policy for additional details):

a. The permittee is properly implementing the CCAA/SHA/HCP and is expected to continue to do so for the term of the agreement. A CCAA/SHA/HCP is properly implemented if the permittee is, and has been, fully implementing the commitments and provisions in the CCAA/SHA/HCP, implementing agreement, and permit.

b. The species for which critical habitat is being designated is a covered species in the CCAA/SHA/HCP, or very similar in its habitat requirements to a covered species. The recognition that we extend to such an agreement depends on the degree to which the conservation measures undertaken in the CCAA/SHA/HCP would also protect the habitat features of the similar species.

c. The CCAA/SHA/HCP specifically addresses the habitat of the species for which critical habitat is being designated and meets the conservation needs of the species in the planning area.

The critical habitat designation as proposed included areas that are covered by the following permitted plan providing for the conservation of 7 of the 12 Hawai'i Island species, as specified below:

Safe Harbor Agreement Trustees of the Estate of Bernice P. Bishop, DBA, Kamehameha Schools Keauhou and Kīlauea Forest Lands Hawai'i Island, Hawai'i (Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement), June 2017—The permit holder for this SHA is Kamehameha Schools. Kamehameha Schools was established in 1887, through the will of Princess Bernice Pauahi Paki Bishop. Kamehameha Schools owns more than 362,000 ac (146,496 ha) of land throughout Hawaii, and part of Kamehameha Schools' mission is to protect Hawaii's environment through recognition of the significant cultural value of this land and its unique flora and fauna. In 2017, the SHA was approved by the Service and Hawaii Department of Land and Natural Resources for the Kamehameha School's Keauhou and Kīlauea Forest lands, which comprise 32,280 ac (13,063 ha) on the east slope of Mauna Loa Volcano, on the island of Hawai'i.

Under the SHA, koa (*Acacia koa*) tree silviculture will be conducted, including stand improvement through selective harvest and establishment of new or improvement of existing forest in formerly logged areas and degraded pasture lands (Kamehameha Schools 2017, pp. 22–23). The conservation actions of Kamehameha Schools benefit habitat for *Cyanea tritomantha, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* by promoting forest regeneration, which increases soil-water retention capacity and improves ecosystem resilience to drying climate conditions; controlling feral ungulates, which reduces trampling of and predation on these plants, including the host plants of *Drosophila digressa;* controlling weeds, which improves recruitment of native trees, including those that host *Drosophila digressa;* and taking actions that reduce the incidence of fire, which benefits forest habitat for these species by minimizing damage to that habitat by wildfire.

We considered the following areas for exclusion from the critical habitat designation on Hawai'i Island based on this permitted plan:

Plant Unit 51 and Drosophila digressa—Unit 2—The Kamehameha Schools are responsible for 93 ac (38 ha) of land included in the proposed critical habitat designation for Unit 51 which overlap a portion of *Drosophila digressa*—Unit 2. Conservation management actions on these lands occur under the Kamehameha Schools Keauhou and Kīlauea Forest Lands SHA. This SHA is implemented effectively; specifically addresses habitat for *Cyanea tritomantha, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa;* and meets the conservation needs for these species in the planning area. In addition to this SHA, this area in Unit 51 is also covered under two non-permitted conservation plans, the Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program and the Three Mountain Alliance Management Plan (as described below). Both non-permitted conservation plans are summarized below in ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' We provide a detailed balancing analysis for 93 ac (38 ha) in Unit 51 and *Drosophila digressa*—Unit 2 for exclusion from the final critical habitat designation because conservation actions occurring on the ground, including forest restoration, fire control measures, ungulate fence installation and maintenance, and control of invasive introduced plants, provide a conservation benefit to 7 of the 12 Hawai'i Island species, as specified below.

Non-Permitted Conservation Plans, Agreements, or Partnerships

Shown below is a non-exhaustive list of factors that we consider in evaluating how non-permitted plans or agreements affect the benefits of inclusion or exclusion. These are not required elements of plans or agreements. Rather, they are some of the factors we may consider, and not all of these factors apply to every plan or agreement.

(i) The degree to which the record of the plan, or information provided by proponents of an exclusion, supports a conclusion that a critical habitat designation would impair the realization of the benefits expected from the plan, agreement, or partnership.

(ii) The extent of public participation in the development of the conservation plan.

(iii) The degree to which agency review and required determinations (*e.g.,* State regulatory requirements) have been completed, as necessary and appropriate.

(iv) Whether NEPA compliance was required.

(v) The demonstrated implementation and success of the chosen mechanism.

(vi) The degree to which the plan or agreement provides for the conservation of the physical or biological features that are essential to the conservation of the species.

(vii) Whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan or agreement will be implemented.

(viii) Whether the plan or agreement contains a monitoring program and adaptive management to ensure that the conservation measures are effective and can be modified in the future in response to new information.

The critical habitat designation includes areas that are covered by the following non-permitted plans providing for the conservation of one or more of the 12 Hawai'i Island species as specified below:

I. Watershed Partnerships

a. Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan

The Mauna Kea Watershed Alliance Watershed Partnership is a coalition of private and public landowners and supporting agencies working to protect and restore watershed areas on Mauna Kea Volcano, Hawai'i (Mauna Kea Watershed Alliance 2022, entire). Lands that are managed by the Mauna Kea Watershed Alliance include more than 500,000 ac (202,343 ha) on Mauna Kea Volcano on the island of Hawai'i. The Mauna Kea Watershed Alliance's shared vision is to protect and enhance watershed ecosystems, biodiversity, and natural resources through responsible management while promoting economic sustainability and providing recreational, subsistence, educational, and research opportunities. Staff of the Mauna Kea Watershed Alliance work cooperatively with landowners of the alliance to achieve this shared vision. Accordingly, fencing and ungulate control, control of introduced plants that are invasive, and reforestation efforts are conducted on lands within the Mauna Kea Watershed Alliance (Stewart 2010, p. viii). Ungulate control benefits habitat for *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* by reducing the trampling of and predation on these plants, including the host plants of *Drosophila digressa,* leading to improved forest regeneration. Nonnative plant control improves recruitment of native trees, including host plants of *Drosophila digressa,* and reforestation provides greater areas of native plant associations that contribute to habitat and increases soil-water retention capacity, improving ecosystem resilience to drying climate conditions.

b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan

The Kohala Watershed Partnership is a coalition of private and public landowners and supporting agencies whose goal is to show improvements in water and environmental quality by enabling comprehensive and sustainable watershed management projects that address the threats to the watershed, while maintaining its integrity and protecting its economic, socio-cultural, and ecological resources (Kohala Watershed Partnership (KWP) 2007, p. 3). Lands that are managed by Kohala Mountain Watershed Management Plan include approximately 68,000 ac (27,519 ha) of forest and grass lands on the windward and leeward slopes of the Kohala Volcano on the island of Hawai'i (KWP 2007, p. 3). Conservation measures of this plan benefit habitat for *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* by promoting native forest and shrubland regeneration and increasing soil-water retention capacity through control of feral ungulates and weed control that improves recruitment of native trees and shrubs. Wildfire management and response benefits coastal habitat, forest, and shrubland habitats used by these species by minimizing fire damage (KWP 2007, pp. 62–82).

c. Three Mountain Alliance Watershed Partnership and the Three Mountain Alliance Management Plan

The Three Mountain Alliance Watershed Partnership is a coalition of private and public landowners and supporting agencies that are working to protect and restore watershed areas on Hawai'i Island (Three Mountain Alliance Management Plan (TMA) 2007, entire). Lands that are managed by the Three Mountain Alliance are 1,116,300 ac (451,751 ha) on Mauna Loa, Kīlauea, and Hualālai volcanoes or roughly 45 percent of the island of Hawai'i. Project funding for the Three Mountain Alliance currently comes from Three Mountain Alliance members (primarily the Service, Hawaiis DOFAW, and Kamehameha Schools) and outside grants. Other Three Mountain Alliance members provide in-kind services to accomplish priority projects, for example, inmate labor or sharing personnel and equipment (TMA 2007, p. 56). Management under the Three Mountain Alliance Management Plan includes the following conservation actions: (1) strategic fencing and removal of ungulates; (2) regular monitoring for ungulates after fencing; (3) monitoring of habitat recovery; (4) surveys for rare taxa prior to new fence installations; (5) invasive, nonnative plant control; (6) reestablishment of native plant species; and (7) activities to reduce the threat of wildfire. Ungulate control reduces damage to native forests, including to host plants of *Drosophila digressa;* control of nonnative, invasive plants and out-planting of native plants, including host plants of *Drosophila digressa,* improves recruitment of native trees; and fire suppression activities reduce the damage from wildfires to habitats used by *Cyanea marksii, Cyanea tritomantha, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa.*

II. Other Partnerships

a. Parker Ranch Sustainable Forestry Initiative

Parker Ranch was founded in 1847, and currently encompasses more than 100,000 ac (40,469 ha) of land in the Hamakua, North Kohala, and South Kohala Districts on Mauna Kea and the Kohala Mountains on the island of Hawai'i. Parker Ranch recognizes forest health as a key indicator of overall ecosystem health and, as result, announced in 2021 that it is seeking to collaborate with public and private partners to develop sustainable forestry programs on its lands (Parker Ranch 2021, entire).

For its Waipunalei lands on the eastern slope of Mauna Kea, Parker Ranch is developing a sustainable forestry program and is seeking to rehabilitate forest areas damaged by cattle grazing. In 2021, Parker Ranch fenced the Waipunalei Forestry Unit, a 1,500-ac (607-ha) parcel, and is removing feral grazing animals.

Waipunalei is managed to reduce threats to the native forest ecosystem and increase native forest canopy. Over the next 3 years, thousands of native seedlings will be planted, and weeds will be controlled across approximately 650 ac (263 ha) within the Waipunalei Forestry Unit (Parker Ranch 2023, pers. comm.).

For its Waiemi lands on the Kohala Mountains, Parker Ranch is providing essential access and support to the State Department of Land and Natural Resources for priority watershed projects in Pu'u o Umi Natural Area Reserve and is supporting erosion control efforts above Pelekane Bay (Parker Ranch 2021, pers. comm.).

Additionally, Parker Ranch is a member of the Mauna Kea Watershed Alliance (see ''a. Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan,'' above). Koa forestry benefits forest habitat used by *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* by establishing new or improving forest in formerly logged areas and degraded pasture lands, increasing soil-water retention capacity, and improving ecosystem resilience to drying climate conditions through control of feral ungulates and weed control that improves recruitment of native trees, including the host plants of *Drosophila digressa.*

b. Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program

Kamehameha Schools owns more than 362,000 ac (146,496 ha) of land throughout Hawai'i. Part of Kamehameha Schools' mission is to protect Hawaii's environment through recognition of the significant cultural value of this land and its unique flora and fauna. Accordingly, Kamehameha Schools established a sustainable stewardship policy to guide the use of its lands through their ʻĀina Pauahi Natural Resources Management Program that includes the protection and conservation of natural resources, water resources, and ancestral places (Kamehameha Schools 2022, entire).

Between 2000 and 2015, Kamehameha Schools increased active stewardship of native ecosystems by over 35-fold, from 3,000 ac (1,124 ha) to 136,000 ac (55,037 ha); engaged in community collaborations to leverage external resources in support of culturally appropriate land stewardship; and developed and implemented its 2012 natural resource and cultural resource management plans representing Kamehameha Schools' responsibility to conduct prudent stewardship of the ʻāina (land). Kamehameha Schools manages some of its forested lands for income generation through sustainable koa and ʻiliahi or sandalwood (*Santalum album*) forestry and collaborates with county and other landowners in fire response planning to protect natural resources from fires. Fire suppression protects native forests and shrubland habitats from wildfire. These actions promote regeneration of native forests that support the 12 Hawai'i Island species.

c. Department of Hawaiian Home Lands ʻĀina Mauna Legacy Program

The Department of Hawaiian Home Lands is governed by the Hawaiian Homes Commission Act of 1920, enacted by the U.S. Congress to protect and improve the lives of native Hawaiians. The Hawaiian Homes Commission Act of 1920 created a Hawaiian Homes Commission to administer certain public lands, called Hawaiian homelands, for native Hawaiian homesteads. These lands are not considered public lands in the general sense. The primary responsibilities of the Department of Hawaiian Home Lands are to serve its beneficiaries and to manage its extensive land trust, which consists of more than 200,000 ac (80,937 ha) on the islands of Hawai'i, Maui, Moloka'i, Lāna'i, O'ahu, and Kaua'i.

The goal of the Department of Hawaiian Home Lands' ʻĀina Mauna Legacy Program is to restore and protect approximately 56,000 ac (22,662 ha) of native Hawaiian forest on Mauna Kea Volcano on the island of Hawai'i that is ecologically, culturally, and economically self-sustaining for the Hawaiian Home Lands Trust, its beneficiaries, and the community (Department of Hawaiian Home Lands 2009, p. 7). The Department of Hawaiian Home Lands ʻĀina Mauna Legacy Program describes activities to be conducted on Department of Hawaiian Home Lands lands over the next 100 years, including native forest restoration and sustainable koa forestry; invasive plant control and remnant invasive species eradication; nonnative wildlife control and management (*i.e.,* feral ungulate control); road system, fencing, and water systems infrastructure development and maintenance; and research and community outreach.

Some forest areas in lands managed under the ʻĀina Mauna Legacy Program are degraded by a history of cattle grazing. Koa tree silviculture is in initial stages and will be conducted (at least during the next 100 years) on lands under this management designation, including stand improvement through selective harvest and establishment of new or improved forest in formerly logged areas and degraded pasture lands. Koa silviculture benefits habitat for the 12 species addressed in this final critical habitat designation by establishing new or improved forest, increasing soil-water retention capacity, and improving ecosystem resilience to drying climate conditions. Ungulate control reduces damage to ʻōhiʻa forests, maintains forest health, and prevents ungulates from degrading habitat for the 12 species addressed in this final critical habitat designation. Control of nonnative, invasive plants and out-planting of native plants improves recruitment of native trees.

d. The Nature Conservancy Forest Stewardship Management Plan for the Kona Hema Preserve

The Nature Conservancy Kona Hema Preserve was established in 1999, in the South Kona District of the island of Hawai'i. It is comprised of 8,076 ac (3,268 ha) in four management units. The management program for Kona Hema Preserve is documented in The Nature Conservancy's Forest Stewardship Management Plan for the Kona Hema Preserve, which details management measures to protect, restore, and enhance rare plants and animals and their habitats within the preserve and in adjacent areas (The Nature Conservancy 2017, entire).

The primary management goals for the Kona Hema Preserve are to: (1) prevent degradation of native forest and shrubland by reducing feral ungulate damage; (2) improve or maintain the integrity of native ecosystems in selected areas of the preserve by reducing the effects of nonnative plants; (3) conduct small mammal control and reduce the negative impacts of small mammals where possible; (4) monitor and track the biological and physical resources in the preserve, evaluate changes in these resources over time, and encourage biological and environmental research; (5) prevent extinction of rare species in the preserve; (6) build public understanding and support for the preservation of natural areas, and enlist volunteer assistance for preserve management; and (7) protect the resources from fires in and around the preserve. Ungulate control reduces damage to ʻōhiʻa forests, maintains forest health, and prevents ungulates from degrading habitat for the 12 species addressed in this final critical habitat designation. Fire suppression reduces the damage from wildfires and provides protection for

forest and shrubland habitat. Invasive plant control improves recruitment of native trees, and small mammal control, particularly rat (*Rattus* spp.) control, reduces the potential for seed predation by rats on the plant species addressed in this final critical habitat designation.

Permitted and Non-Permitted Plans in Critical Habitat Units

The Nature Conservancy manages 986 ac (399 ha) of land in plant Unit 41 and *Drosophila digressa*—Unit 5 that we identified as lands we were considering for exclusion in our March 29, 2023, proposed rule (88 FR 18756). The Nature Conservancy benefits habitat of *Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae,* in plant Unit 41, and *Drosophila digressa* in *Drosophila digressa*—Unit 5, with conservation and management activities through The Nature Conservancy's Forest Stewardship Management Plan for the Kona Hema Preserve, and the Three Mountain Alliance Watershed Partnership and the Three Mountain Alliance Management Plan, described above. The Nature Conservancy lands in plant Unit 41 and *Drosophila digressa*—Unit 5 are within their Kona Hema Preserve, where they are actively conducting ungulate removal and native forest restoration, including invasive weed removal, to improve the habitat for all six species listed above.

We had considered excluding the 986-ac (399-ha) parcel of Nature Conservancy land in plant Unit 41 and *Drosophila digressa*—Unit 5, but during the comment period on our March 29, 2023, proposed rule (88 FR 18756), we received a request from The Nature Conservancy to include their 986-ac (399-ha) parcel in our final critical habitat designation, rather than exclude it. The Nature Conservancy expects that the inclusion of their Kona Hema Preserve lands in this final critical habitat designation will increase their potential to develop partnerships and implement conservation in the future for these species or for other federally listed and sensitive species in neighboring parcels.

Therefore, because the 986 ac (399 ha) owned by The Nature Conservancy in plant Unit 41 and *Drosophila digressa*—Unit 5 meets the definition of critical habitat for *Cyanea marksii, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa,* and The Nature Conservancy supports the inclusion of their parcel in our designation, we are including this parcel in our final critical habitat designation without further investigation into potential benefits from excluding it.

In the following discussion, we describe each of the parcels by landowner where we have conducted a balancing analysis and evaluated the benefits of inclusion in the critical habitat designation, the benefits of exclusion, our determination of whether the benefits of exclusion or inclusion are greater, and if exclusion would result in the extinction of the species. Specifically, we explain the benefit to the species of the watershed partnerships, permitted plans, or other non-permitted conservation plans, agreements, or partnerships, as well as other conservation actions implemented on certain lands that we have included in our balancing analysis and how the non-permitted conservation or management plans satisfy the non-exhaustive list of factors provided above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' that we may choose to consider in our evaluation. We indicate the acreage in each unit that we are excluding from the critical habitat designation based on our analysis.

I. Parker Ranch Lands

Parker Ranch manages two parcels of land (403 ac (163 ha) and 372 ac (151 ha)) in Units 52 and 54, respectively. These parcels were identified as lands we were considering for exclusion in our March 29, 2023, proposed rule (88 FR 18756). As stated in table 3, the boundary for *Drosophila digressa*—Unit 1 is identical to Section 1 (plant Units 3 and 52, combined).

In the March 29, 2023, proposed rule, we reference an additional area of 547 ac (221 ha) in plant Unit 3 that is owned and managed by Parker Ranch but would not be considered for exclusion because it overlaps with existing critical habitat already designated for other species. During that proposed rule's public comment period, we held several meetings with Parker Ranch to answer questions regarding the critical habitat designation and obtain additional information concerning the management of their lands. During those discussions, Parker Ranch was supportive of the exclusion of their lands we were considering in Units 52 and 54, and was not interested in having the remaining 547 ac (221 ha) that are already designated for other species be a part of that exclusion. Further, we received no subsequent request from Parker Ranch that the 547-ac (221-ha) area be excluded, and therefore it remains in this final critical habitat designation.

Conservation and management activities on Parker Ranch lands in Units 52 and 54, as well as *Drosophila digressa*—Unit 1, include those associated with Parker Ranch's Sustainable Forestry Initiative and Mauna Kea Watershed Alliance (see ''a. Parker Ranch Sustainable Forestry Initiative'' under II. *Other Partnerships* and ''*a. Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan*'' *under I. Watership Partnerships,* above). Conservation measures of Parker Ranch, through its Sustainable Forestry Initiative, benefit habitat for all species within Units 52 and 54 including *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa.*

Parker Ranch lands in Unit 52 are within their Waipunalei Forestry Unit, where Parker Ranch is actively conducting ungulate removal and native forest restoration, including invasive weed removal to support the habitat for all eight species within Unit 52. In Unit 54, within its Waiemi lands, Parker Ranch is providing essential access and support to the Hawaii State Department of Land and Natural Resources for priority watershed projects in Pu'u o Umi Natural Area Reserve and is supporting erosion control efforts above Pelekane Bay (Parker Ranch 2021, pers. comm.). Additionally, Parker Ranch is a member of the Mauna Kea Watershed Alliance (see ''*a. Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan*'' *under I. Watership Partnerships,* above). Parker Ranch's koa forestry activities benefit forest habitat used by *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* by establishing new or improved forest in formerly logged areas and degraded pasture lands, increasing soil-water retention capacity, and improving ecosystem resilience to drying climate conditions through control of feral ungulates and weed control that improves recruitment of native trees, including the host plants of *Drosophila digressa.*

Based on Parker Ranch's management, Parker Ranch's Sustainable Forestry Initiative and participation in the Mauna Kea Watershed Alliance, we evaluated 403 ac (163 ha) in Unit 52 and *Drosophila digressa*—Unit 1, and 372 ac (151 ha) in Unit 54, of lands owned by Parker Ranch to determine if excluding these lands from the final critical habitat designation is appropriate.

Benefits of Inclusion—Parker Ranch

The principal benefit of including an area in critical habitat designation is the requirement under section 7(a)(2) of the Act that Federal agencies ensure, in consultation with the Service, that actions that they fund, authorize, or carry out are not likely to result in the destruction or adverse modification of any designated critical habitat. Federal agencies must also consult with the Service on actions that may affect a listed species and refrain from actions that are likely to jeopardize the continued existence of such species. If the Service determines that the Federal action is likely to jeopardize the continued existence of the species, or result in the destruction or adverse modification of critical habitat, it will identify reasonable and prudent alternatives to the Federal action to avoid such results. The Service's analysis of effects to critical habitat (to determine whether destruction or adverse modification is likely) is a separate and different analysis from the Service's analysis of the effects to the species to determine whether jeopardy to the species is likely. Therefore, the difference in outcomes of these two analyses represents the regulatory benefit of critical habitat.

For some actions, the outcome of these analyses will be similar, because effects from a Federal action to habitat will often also result in effects to the species. However, the regulatory standards are distinct for each. For the jeopardy analysis, the Service evaluates whether the action reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species. For the destruction or adverse modification analysis for critical habitat, the Service evaluates whether the action results in a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of the listed species. Thus, the critical habitat designation can confer additional protection to a species other than listing alone, particularly if the proposed Federal action does not itself impact individuals of the species, but does impact its critical habitat. Therefore, critical habitat designation may provide a regulatory benefit for *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* on lands owned by Parker Ranch in plant Units 52 and 54, and *Drosophila digressa*—Unit 1.

Another possible benefit of including lands in critical habitat is public education regarding the potential conservation value of an area that may help focus conservation efforts on areas of high conservation value for certain species. We consider any information about *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* and their habitat that reaches a wide audience, including parties engaged in conservation activities, to be valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of the species in these units.

Therefore, because activities with a Federal nexus will require section 7 consultations, and because of the occurrence of these species on Parker Ranch lands, it is expected that there may be some, but limited, benefits from including Parker Ranch lands in plant Units 52 and 54, and in *Drosophila digressa*—Unit 1, in the critical habitat designation. The principal benefit of any designated critical habitat is that activities in and affecting such habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid destruction or adverse modification of critical habitat.

Benefits of Exclusion—Parker Ranch

The benefits of excluding two parcels—one in plant Unit 52 and *Drosophila digressa*—Unit 1 (403 ac (163 ha)) and the other in plant Unit 54 (372 ac (151ha))—owned by Parker Ranch from this designation of critical habitat include: (1) the continued implementation of conservation plans (Parker Ranch's Sustainable Forestry Initiative and the Mauna Kea Watershed Management Plan) that include actions that benefit *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa;* (2) strengthening of our effective partnership with Parker Ranch and other neighboring landowners to promote voluntary, proactive conservation of *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* and their habitats; (3) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation benefits that might not otherwise occur; and (4) encouragement of developing and implementing conservation and management plans in the future for these species or other federally listed and sensitive species.

In some cases, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1,265; Bean 1998, p. 10706). The magnitude of this negative outcome is amplified in situations where active management measures (such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 1998, pp. 10706–10708). We find that the exclusion of these specific areas of non-federally owned lands from this critical habitat designation can contribute to the species' recovery and provide a superior level of conservation than critical habitat designation can provide alone. We have also found that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 1998, entire). Additionally, partnerships with non-Federal landowners are vital to the conservation of these species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions.

Excluding lands owned and managed by Parker Ranch in plant Unit 52 and *Drosophila digressa*—Unit 1, and in plant Unit 54, from critical habitat will help foster the partnerships the landowners and land managers have developed with Federal and State agencies and local conservation organizations, will encourage the continued implementation of voluntary conservation actions for the benefit of the species and their habitats on these lands, and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive effect of excluding from critical habitat areas managed by active conservation partners to be a significant benefit of exclusion.

Benefits of Exclusion Outweigh the Benefits of Inclusion—Parker Ranch

We evaluated approximately 403 ac (163 ha) in Unit 52 and *Drosophila digressa*—Unit 1, and 372 ac (151 ha) in Unit 54, owned by Parker Ranch for exclusion from this designation of critical habitat. We determined the benefits of excluding these lands outweigh the benefits of including them as critical habitat for 12 species on Hawai'i Island. While Parker Ranch may receive Federal grants (actions which carry a Federal nexus) occasionally, all areas of Parker Ranch lands being evaluated for exclusion are occupied by one or more of the 12 species addressed in this final rule. Because these areas are occupied, the few section 7 consultations that may occur would include an analysis of the effects to the species under the jeopardy analysis, as described above. We expect that conservation measures that the Service would consider in addressing effects to the species under a jeopardy analysis would be very similar to those to address effects to the critical habitat under an adverse modification analysis. As such, we conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small because of the limited distinction between actions to avoid jeopardy and adverse modification. These marginal regulatory benefits of inclusion are further reduced by the existence of conservation plans and implemented actions, which include habitat conservation that addresses the special management considerations. Furthermore, the potential educational and informational benefits of critical habitat designation on areas of the Parker Ranch containing the physical and biological features essential to the conservation of *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* would be minimal because the landowners have demonstrated their knowledge of the species and their habitat needs in the process of developing conservation partnerships with the Service and others.

In contrast, the benefits derived from excluding the lands owned by Parker Ranch and enhancing our partnership with this landowner are significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in Hawaii, a State with relatively little Federal land ownership but many species of conservation concern. Excluding these areas on the Parker Ranch from critical habitat will help foster the partnerships Parker Ranch has developed with Federal and State agencies and local conservation organizations, and will encourage the continued implementation of voluntary conservation actions for the benefit of *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* and their habitats.

The current active conservation efforts on Parker Ranch lands in Unit 52 (*Drosophila digressa*—Unit 1) and Unit 54 benefit these species, satisfying factor (vi) of the section 4(b)(2) exclusion analysis, as described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The partnerships and management plans are longstanding and have demonstrated implementation and success, and we have a reasonable expectation that the conservation management strategies or actions in the plans will be implemented, satisfying factors (v) and (vii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The Parker Ranch's Sustainable Forestry Initiative and the Mauna Kea Watershed Management Plan include multiple objectives that satisfy factor (viii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' by promoting monitoring and adaptive management to ensure conservation measures are effective. In addition, these partnerships not only provide a benefit for the conservation of these species but may also serve as a model and aid in fostering future cooperative relationships with other parties in these areas of Hawai'i and in other locations for the benefit of other endangered or threatened species.

Management by Parker Ranch through participation in the Mauna Kea Watershed Management Plan and implementation of their Sustainable Forestry Initiative provides significant habitat protection for *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa.* We find that excluding areas from critical habitat that are under these long-term conservation and management plans to protect the habitat that supports these species will preserve our partnership with Parker Ranch in the State of Hawaii and will encourage future collaboration towards conservation and recovery of listed species. In summary, these partnership benefits to the subject species outweigh the small potential regulatory, educational, and ancillary benefits of including Parker Ranch lands in this final critical habitat designation.

Exclusion Will Not Result in Extinction of the Species—Parker Ranch

We determined that the exclusion of approximately 403 ac (163 ha) in Unit 52 and *Drosophila digressa*—Unit 1, and 372 ac (151 ha) in Unit 54, owned by Parker Ranch from this designation of critical habitat will not result in the extinction of *Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* or *Drosophila digressa.* Protections afforded to these species based on their listed status, and afforded to their habitats by the management and conservation plans, provide assurances that these species will not go extinct as a result of excluding these lands from the critical habitat designation.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that a critical habitat designation does not necessarily require affirmative actions to restore or actively manage critical habitat for the benefit of listed species; the regulatory effect of critical habitat is that Federal agencies must ensure (though consultation with the Service) that any activity they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. It is, therefore, advantageous for the conservation of these species to support the proactive efforts of non-Federal landowners who are contributing to the further enhancement of essential habitat features that support recovery of listed species through exclusion of their lands from a critical habitat designation. The jeopardy standard of section 7 of the Act will continue to provide protection to listed species in these areas when there is a Federal nexus.

II. Laupāhoehoe Nui Lands

Laupāhoehoe Nui manages two parcels of land (134 ac (54 ha) and 134 ac (54 ha)) in Units 53 and 54, respectively. These parcels were

identified as lands we were considering for exclusion in our March 29, 2023, proposed rule (88 FR 18756).

Conservation and management activities on Laupāhoehoe Nui lands in Units 53 and 54 include those associated with the Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan (see ''*b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan*'' *under I. Watershed Partnerships,* above). Conservation measures of Laupāhoehoe Nui, through the Kohala Mountain Watershed Management Plan, benefit habitat for all species within Units 53 and 54 including *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.*

Laupāhoehoe Nui lands in Unit 53 are managed by the Kohala Mountain Watershed Management Plan, where the Kohala Watershed Partnership is actively conducting ungulate removal and native forest restoration, including invasive weed removal to support the habitat for *Bidens hillebrandiana* ssp. *hillebrandiana.* In Unit 54, within its Upper Laupāhoehoe Nui Watershed Reserve, Laupāhoehoe Nui and the Kohala Watershed Partnership protected 2,000 ac (809 ha) important for aquifer recharge areas on Kohala Mountain, globally rare montane bog ecosystems, seabird nesting areas, and rare and endangered native plants (The Kohala Center 2019, p. 3). Laupāhoehoe Nui's Upper Laupāhoehoe Watershed Reserve benefits forest habitat used by *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* by restoring native forest in degraded lands, increasing soil-water retention capacity, and improving ecosystem resilience to drying climate conditions through control of feral ungulates and weed control that improves recruitment of native trees.

Based on Laupāhoehoe Nui's management of its land under the Kohala Mountain Watershed Management Plan and participation in the Kohala Watershed Partnership, we evaluated 134 ac (54 ha) in Unit 53 and 134 ac (54 ha) in Unit 54 of lands owned by Laupāhoehoe Nui to determine if excluding these lands from the final critical habitat designation is appropriate.

Benefits of Inclusion—Laupāhoehoe Nui

As described above under ''Benefits of Inclusion—Parker Ranch,'' the principal benefit of including an area in critical habitat designation is the requirement of Federal agencies to consult with the Service on actions that may affect the critical habitat. This allows the Service to assess whether Federal actions authorized, funded, or carried out are likely to result in the destruction or adverse modification of designated critical habitat and, if so, to identify alternatives to avoid that result; this is in addition to assessing whether the Federal action is likely to jeopardize the listed species. Thus, the critical habitat designation may provide greater benefits to the species than the listing would alone. Therefore, critical habitat designation may provide a regulatory benefit for *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* on lands owned by Laupāhoehoe Nui in Units 53 and 54.

Another possible benefit of including lands in critical habitat is public education regarding the potential conservation value of an area that may help focus conservation efforts on areas of high conservation value for certain species. We consider any information about *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats that reaches a wide audience, including parties engaged in conservation activities, to be valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of the species in these units.

Therefore, because activities with a Federal nexus will require section 7 consultations, and because of the occurrence of these species on Laupāhoehoe Nui lands, it is expected that there may be some, but limited, benefits from including Laupāhoehoe Nui lands in Units 53 and 54 in the critical habitat designation. The principal benefit of any designated critical habitat is that activities in and affecting such habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid destruction or adverse modification of critical habitat.

Benefits of Exclusion—Laupāhoehoe Nui

The benefits of excluding two parcels—one in Unit 53 (134 ac (54 ha)) and the other in Unit 54 (134 ac (54 ha))—owned by Laupāhoehoe Nui from this designation of critical habitat include: (1) the continued implementation of the conservation plan (Kohala Mountain Watershed Management Plan) that include actions that benefit *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae;* (2) strengthening of our effective partnership with Laupāhoehoe Nui and other neighboring landowners to promote voluntary, proactive conservation of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitat; (3) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation benefits that might not otherwise occur; and (4) encouragement of developing and implementing conservation and management plans in the future for these species or other federally listed and sensitive species.

In some cases, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1,265; Bean 1998, p. 10706). The magnitude of this negative outcome is amplified in situations where active management measures (such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 1998, pp. 10706–10708). We find that the exclusion of these specific areas of non-federally owned lands from this critical habitat designation can contribute to the species' recovery and provide a superior level of conservation than critical habitat designation can provide alone. We have also found that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 1998, entire). Additionally, partnerships with non-Federal landowners are vital to the conservation of these species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions.

Excluding lands owned and managed by Laupāhoehoe Nui in Units 53 and 54 from critical habitat will help foster the partnerships the landowners and land managers have developed with Federal and State agencies and local conservation organizations, will encourage the continued implementation of voluntary conservation actions for the benefit of the species and their habitats on these lands, and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive effect of excluding from critical habitat areas managed by active conservation partners to be a significant benefit of exclusion.

Benefits of Exclusion Outweigh the Benefits of Inclusion—Laupāhoehoe Nui

We evaluated approximately 134 ac (54 ha) in Unit 53 and 134 ac (54 ha) in Unit 54 owned by Laupāhoehoe Nui for exclusion from this designation of critical habitat. We determined the benefits of excluding these lands outweigh the benefits of including them as critical habitat in this designation. We conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small because of the limited distinction between actions to avoid jeopardy and adverse modification. While Laupāhoehoe Nui may receive Federal grants (actions which carry a Federal nexus) from time to time, all areas of Laupāhoehoe Nui lands being evaluated are occupied by one or more of the 12 species addressed in this final rule. Therefore, the few section 7 consultations that may occur will include a jeopardy analysis, as described above, and conservation measures that apply to a jeopardy analysis are expected to be similar to those that apply to an adverse modification analysis. These marginal regulatory benefits are further reduced by the existence of conservation plans and implemented actions, which include habitat conservation that addresses the special management considerations. Furthermore, the potential educational and informational benefits of critical habitat designation on areas containing the physical and biological features essential to the conservation of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* would be minimal because the landowner has demonstrated their knowledge of the species and their habitat needs in the process of developing conservation partnerships with the Service and others.

In contrast, the benefits derived from excluding the lands owned by Laupāhoehoe Nui and enhancing our partnership with this landowner are significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in Hawaii, a State with relatively little Federal land ownership but many species of conservation concern. Excluding these areas from critical habitat will help foster the partnerships the landowners and land managers in question have developed with Federal and State agencies and local conservation organizations and will encourage the continued implementation of voluntary conservation actions for the benefit of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats on these lands.

The current active conservation efforts on Laupāhoehoe Nui lands in Units 53 and 54 benefit these species, satisfying factor (vi) of the section 4(b)(2) exclusion analysis, as described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The partnership and management plan are longstanding and have demonstrated implementation and success, and we have a reasonable expectation that the conservation management strategies or actions in the plan will be implemented, satisfying factors (v) and (vii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The Kohala Mountain Watershed Management Plan includes multiple objectives that satisfy factor (viii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' by promoting monitoring and adaptive management to ensure conservation measures are effective. In addition, this partnership not only provides a benefit for the conservation of these species but may also serve as a model and aid in fostering future cooperative relationships with other parties in these areas of Hawaii and in other locations for the benefit of other endangered or threatened species.

Management by Laupāhoehoe Nui through participation in the Kohala Mountain Watershed Management Plan and Kohala Watershed Partnership provides significant habitat protection for *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.* We find that excluding areas from critical habitat that are under long-term conservation and management plans to protect the habitat that supports these species will preserve our partnership with Laupāhoehoe Nui in the State of Hawaii and will encourage future collaboration towards conservation and recovery of listed species. In summary, these partnership benefits to the subject species outweigh the small potential regulatory, educational, and ancillary benefits of including the Laupāhoehoe Nui lands in this final critical habitat designation.

Exclusion Will Not Result in Extinction of the Species—Laupāhoehoe Nui

We determined that the exclusion of approximately 134 ac (54 ha) in Unit 53 and 134 ac (54 ha) in Unit 54 owned by Laupāhoehoe Nui from this designation of critical habitat will not result in the extinction of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* or *Stenogyne cranwelliae.* Protections afforded to these species based on their listed status, and afforded to their habitats by the management and conservation plan, provide assurances that these species will not go extinct as a result of excluding these lands from the critical habitat designation.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that a critical habitat designation does not necessarily require affirmative actions to restore or actively manage critical habitat for the benefit of listed species; the regulatory effect of critical habitat is that Federal agencies must ensure (through consultation with the Service) that any activity they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. It is, therefore, advantageous for the conservation of these species to support the proactive efforts of non-Federal landowners who are contributing to the enhancement of essential habitat features for listed species through

exclusion of their lands from a critical habitat designation. The jeopardy standard of section 7 of the Act will continue to provide protection to listed species in these areas when there is a Federal nexus.

III. State Department of Hawaiian Home Lands

State Department of Hawaiian Home Lands manages one parcel of land (36 ac (15 ha)) in Unit 54. This parcel was identified as land we were considering for exclusion in our March 29, 2023, proposed rule (88 FR 18756).

Conservation and management activities on the Department of Hawaiian Home Lands include those associated with the Kohala Mountain Watershed Partnership and the Kohala Watershed Management Plan, December 2007 (see ''*b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan*'' *under I. Watershed Partnerships,* above). Conservation measures of the Department of Hawaiian Home Lands through the Kohala Mountain Watershed Management Plan benefit habitat used by *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.*

Based on Department of Hawaiian Home Lands management and participation in the Kohala Mountain Watershed Partnership, we evaluated 36 ac (15 ha) of lands owned by the Department of Hawaiian Home Lands in Unit 54 to determine if excluding these lands from the final critical habitat designation is appropriate.

Benefits of Inclusion—Department of Hawaiian Home Lands

As described above under ''Benefits of Inclusion—Parker Ranch,'' the principal benefit of including an area in critical habitat designation is the requirement of Federal agencies to consult with the Service on actions that may affect the critical habitat. This allows the Service to assess whether Federal actions authorized, funded, or carried out are likely to result in the destruction or adverse modification of designated critical habitat and, if so, to identify alternatives to avoid that result; this is in addition to assessing whether the Federal action is likely to jeopardize the listed species. Thus, critical habitat designation may provide greater benefits to the recovery of a species than the listing would alone. Therefore, critical habitat designation may provide a regulatory benefit for *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* on lands owned by the Department of Hawaiian Home Lands in Unit 54.

Another possible benefit of including lands in critical habitat is public education regarding the potential conservation value of an area that may help focus conservation efforts on areas of high conservation value for certain species. We consider any information about *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats that reaches a wide audience, including parties engaged in conservation activities, to be valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of the species in these units.

Therefore, because activities with a Federal nexus will require section 7 consultations, and because of the occurrence of these species on Department of Hawaiian Home Lands, it is expected that there may be some, but limited, benefits from including Department of Hawaiian Home Lands in Unit 54 in the critical habitat designation. The principal benefit of any designated critical habitat is that activities in and affecting such habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid destruction or adverse modification of critical habitat.

Benefits of Exclusion—Department of Hawaiian Home Lands

The benefits of excluding the 36–ac (15–ha) parcel owned by the Department of Hawaiian Home Lands in Unit 54 from this designation of critical habitat include: (1) the continued implementation of conservation plans (Kohala Mountain Watershed Management Plan) that include actions that benefit *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae;* (2) strengthening of our effective partnership with the Department of Hawaiian Home Lands and other neighboring landowners to promote voluntary, proactive conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats; (3) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation benefits that might not otherwise occur; and (4) encouragement of developing and implementing conservation and management plans in the future for these species or other federally listed and sensitive species.

In some cases, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1,265; Bean 1998, p. 10706). The magnitude of this negative outcome is amplified in situations where active management measures (such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 1998, pp. 10706–10708). We find that the exclusion of these specific areas of non-federally owned lands from this critical habitat designation can contribute to the species' recovery and provide a superior level of conservation than critical habitat designation can provide alone. We have also found that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 1998, entire). Additionally, partnerships with non-Federal landowners are vital to the conservation of these species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions.

Excluding lands owned and managed by the Department of Hawaiian Home Lands in Unit 54 from critical habitat will help foster the partnerships the landowners and land managers have developed with Federal and State agencies and local conservation organizations, will encourage the continued implementation of voluntary conservation actions for the benefit of the species and their habitats on these lands, and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive effect of excluding from critical habitat areas managed by active conservation partners to be a significant benefit of exclusion.

Benefits of Exclusion Outweigh the Benefits of Inclusion—Department of Hawaiian Home Lands

We evaluated 36 ac (15 ha) in Unit 54 owned by the Department of Hawaiian Home Lands for exclusion from this designation of critical habitat. We determined the benefits of excluding these lands outweigh the benefits of including them as critical habitat in this designation. We conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small because of the limited distinction between actions to avoid jeopardy and adverse modification. While the Department of Hawaiian Home Lands may receive Federal grants (actions which carry a Federal nexus) occasionally, all areas of Department of Hawaiian Home Lands being evaluated are occupied by one or more of the 12 species addressed in this final rule. Therefore, the few section 7 consultations that may occur will include a jeopardy analysis, as described above, and conservation measures that apply to a jeopardy analysis are expected to be similar to those that apply to an adverse modification analysis. These marginal regulatory benefits are further reduced by the existence of conservation plans and implemented actions, which include habitat conservation that addresses the special management considerations. Furthermore, the potential educational and informational benefits of critical habitat designation on areas containing the physical and biological features essential to the conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* would be minimal because the Department of Hawaiian Home Lands has demonstrated their knowledge of the species and their habitat needs in the process of developing conservation partnerships with the Service and others.

In contrast, the benefits derived from excluding the lands owned by the Department of Hawaiian Home Lands and enhancing our partnership with this landowner is significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in Hawaii, a State with relatively little Federal land ownership but many species of conservation concern. Excluding these areas from critical habitat will help foster the partnerships the Department of Hawaiian Home Lands and its associated landowners have developed with Federal and State agencies and local conservation organizations and will encourage the continued implementation of voluntary conservation actions for the benefit of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats on this land.

The current active conservation efforts on Department of Hawaiian Home Lands in Unit 54 benefit these species, satisfying factor (vi) of the section 4(b)(2) exclusion analysis, as described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The partnerships and management plans are longstanding and have demonstrated implementation and success, and we have a reasonable expectation that the conservation management strategies or actions in the plans will be implemented, satisfying factors (v) and (vii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The Kohala Mountain Watershed Management Plan includes multiple objectives that satisfy factor (viii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' by promoting monitoring and adaptive management to ensure conservation measures are effective. In addition, these partnerships not only provide a benefit for the conservation of these species but may also serve as a model and aid in fostering future cooperative relationships with other parties in these areas of Hawai'i and in other locations for the benefit of other endangered or threatened species.

Management by Department of Hawaiian Home Lands through participation in the Kohala Mountain Watershed Partnership and the Kohala Watershed Management Plan provides significant habitat protection for *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.* We find that excluding areas from critical habitat that are under long-term conservation and management to protect the habitats of these species will preserve our partnership with the Department of Hawaiian Home Lands in the State of Hawaii and will encourage future collaboration towards conservation and recovery of listed species. In summary, these partnership benefits to the subject species outweigh the small potential regulatory, educational, and ancillary benefits of including the Department of Hawaiian Home Lands parcels in this final critical habitat designation.

Exclusion Will Not Result in Extinction of the Species—Department of Hawaiian Home Lands

We determined that the exclusion of approximately 36 ac (15 ha) in Unit 54 owned by the Department of Hawaiian Home Lands from this designation of critical habitat will not result in the extinction of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* or *Stenogyne cranwelliae.* Protections afforded to these species based on their listed status, and afforded to their habitats by the management and conservation plans, provide assurances that these species will not go extinct as a result of excluding these lands from the critical habitat designation.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that a critical habitat designation does not necessarily require affirmative actions to restore or actively manage critical habitat for the benefit of listed species; the regulatory effect of critical habitat is that Federal agencies must ensure (through consultation with the Service) that any activity they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. It is, therefore, advantageous for the conservation of these species to support the proactive efforts of non-Federal landowners who are contributing to the enhancement of essential habitat features for listed species through exclusion of their lands from a critical habitat designation. The jeopardy standard of section 7 of the Act will continue to provide protection to listed species in these areas when there is a Federal nexus.

IV. Kahua Ranch Lands

Kahua Ranch manages 605 ac (245 ha) of land in Unit 54. This area was identified as land we were considering for exclusion in our March 29, 2023, proposed rule (88 FR 18756).

Conservation and management activities on Kahua Ranch lands in Unit 54 include those associated with Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan (see ''*b. Kohala Watershed Partnership and the Kohala Mountain Watershed*

Management Plan'' under I. Watershed Partnerships, above). Conservation measures of Kahua Ranch, through the Kohala Mountain Watershed Management Plan, benefit habitat for all species within Unit 54, including *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.*

Kahua Ranch lands in Unit 54 are managed according to the Kohala Mountain Watershed Management Plan. In Unit 54, within its Pu'u Pili Biodiversity Preserve, Kahua Ranch, the Kohala Watershed Partnership, and volunteers protected Kahua Ranch lands important for aquifer recharge areas on Kohala Mountain, globally rare cloud forest ecosystems, forest birds, and rare and endangered native plants (The Kohala Center 2019, p. 3). Additionally, Kahua Ranch is a member of the Kohala Watershed Partnership (see ''*b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan*'' *under I. Watershed Partnerships,* above). Kahua Ranch's Biodiversity Preserve benefits forest habitat used by *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* by restoring native forest in degraded pasture lands, increasing soil-water retention capacity, and improving ecosystem resilience to drying climate conditions through control of feral ungulates and weed control that improves recruitment of native trees.

Based on Kahua Ranch's management of its land under the Kohala Mountain Watershed Management Plan and participation in the Kohala Watershed Partnership, we evaluated 605 ac (245 ha) of lands owned by Kahua Ranch in Unit 54 to determine if excluding these lands from the final critical habitat designation is appropriate.

Benefits of Inclusion—Kahua Ranch

As described above under ''Benefits of Inclusion—Parker Ranch,'' the principal benefit of including an area in critical habitat designation is the requirement of Federal agencies to consult with the Service on actions that may affect the critical habitat. This allows the Service to assess whether Federal actions authorized, funded, or carried out are likely to result in the destruction or adverse modification of designated critical habitat and, if so, to identify alternatives to avoid that result; this is in addition to assessing whether the Federal action is likely to jeopardize the listed species. As such, critical habitat designation may provide greater benefits to the species than the listing would alone. Therefore, critical habitat designation may provide a regulatory benefit for *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* on lands owned by Kahua Ranch in Unit 54.

Another possible benefit of including lands in critical habitat is public education regarding the potential conservation value of an area that may help focus conservation efforts on areas of high conservation value for certain species. We consider any information about *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats that reaches a wide audience, including parties engaged in conservation activities, to be valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of the species in these units.

Therefore, because activities with a Federal nexus will require section 7 consultation, and because of the occurrence of these species on Kahua Ranch lands, it is expected that there may be some, but limited, benefits from including Kahua Ranch lands in Unit 54 in the critical habitat designation. The principal benefit of any designated critical habitat is that any activities with a Federal nexus occurring in or affecting such habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid destruction or adverse modification of critical habitat.

Benefits of Exclusion—Kahua Ranch

The benefits of excluding 605 ac (245 ha) owned by Kahua Ranch in Unit 54 from this designation of critical habitat include: (1) the continued implementation of conservation plans (The Kohala Mountain Watershed Management Plan) that include actions that benefit *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae;* (2) strengthening of our effective partnership with Kahua Ranch and other neighboring landowners to promote voluntary, proactive conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats; (3) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation benefits that might not otherwise occur; and (4) encouragement of developing and implementing conservation and management plans in the future for these species or other federally listed and sensitive species.

In some cases, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1,265; Bean 1998, p. 10706). The magnitude of this negative outcome is amplified in situations where active management measures (such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 1998, pp. 10706–10708). We find that the exclusion of these specific areas of non-federally owned lands from this critical habitat designation can contribute to the species' recovery and provide a superior level of conservation than critical habitat designation can provide alone. We have also found that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 1998, entire). Additionally, partnerships with non-Federal landowners are vital to the conservation of these species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions.

Excluding lands owned and managed by Kahua Ranch in Unit 54 from critical habitat will help foster the partnerships the landowners and land managers have developed with Federal and State agencies and local conservation organizations, will encourage the continued implementation of voluntary conservation actions for the benefit of the species and their habitats on these lands, and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive effect of excluding from critical habitat areas managed by active conservation partners to be a significant benefit of exclusion.

Benefits of Exclusion Outweigh the Benefits of Inclusion—Kahua Ranch

We evaluated approximately 605 ac (245 ha) in Unit 54 owned by Kahua

Ranch for exclusion from the designation of critical habitat. We determined the benefits of excluding these lands outweigh the benefits of including them as critical habitat for the subject species on Hawai'i Island. We conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small because of the limited distinction between actions to avoid jeopardy and adverse modification. While Kahua Ranch may receive Federal grants (actions which carry a Federal nexus) occasionally, all areas of Kahua Ranch lands being evaluated are occupied by one or more of the 12 species addressed in this final rule. Therefore, the few section 7 consultations that may occur will include a jeopardy analysis, as described above, and conservation measures that apply to a jeopardy analysis are expected to be similar to those that apply to an adverse modification analysis. These marginal regulatory benefits are further reduced by the existence of conservation plans and implemented actions, which include habitat conservation that addresses the special management considerations. Furthermore, the potential educational and informational benefits of critical habitat designation on areas containing the physical and biological features essential to the conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* would be minimal because Kahua Ranch has demonstrated their knowledge of the species and their habitat needs in the process of developing conservation partnerships with the Service and others.

In contrast, the benefits derived from excluding the lands owned by Kahua Ranch and enhancing our partnership with this landowner are significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in Hawaii, a State with relatively little Federal land ownership but many species of conservation concern. Excluding these areas from critical habitat will help foster the partnerships the landowners and land managers in question have developed with Federal and State agencies and local conservation organizations and will encourage the continued implementation of voluntary conservation actions for the benefit of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats on these lands.

The current active conservation efforts on Kahua Ranch lands in Unit 54 benefit these species, satisfying factor (vi) of the section 4(b)(2) exclusion analysis, as described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The partnerships and management plans are longstanding and have demonstrated implementation and success, and we have a reasonable expectation that the conservation management strategies or actions in the plans will be implemented, satisfying factors (v) and (vii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The Kohala Mountain Watershed Management Plan includes multiple objectives that satisfy factor (viii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' by promoting monitoring and adaptive management to ensure conservation measures are effective. In addition, these partnerships not only provide a benefit for the conservation of these species but may also serve as a model and aid in fostering future cooperative relationships with other parties in these areas of Hawaii and in other locations for the benefit of other endangered or threatened species.

Management by Kahua Ranch through participation in the Kohala Watershed Partnership and implementation of the Kohala Mountain Watershed Management Plan provides significant habitat protection for *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.* We find that excluding areas from critical habitat that are under these long-term conservation and management plans to protect the habitat that supports these species will preserve our partnership with Kahua Ranch in the State of Hawaii and will encourage future collaboration towards conservation and recovery of listed species. In summary, these partnership benefits to the subject species outweigh the small potential regulatory, educational, and ancillary benefits of including the Kahua Ranch lands in this final critical habitat designation.

Exclusion Will Not Result in Extinction of the Species—Kahua Ranch

We determined that the exclusion of approximately 605 ac (245 ha) owned by Kahua Ranch in Unit 54 from this designation of critical habitat will not result in the extinction of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* or *Stenogyne cranwelliae.* Protections afforded to these species based on their listed status, and afforded to their habitats by the management and conservation plans, provide assurances that these species will not go extinct as a result of excluding these lands from the critical habitat designation.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that a critical habitat designation does not necessarily require affirmative actions to restore or actively manage critical habitat for the benefit of listed species; the regulatory effect of critical habitat is that Federal agencies must ensure (through consultation with the Service) that any activity they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. It is, therefore, advantageous for the conservation of these species to support the proactive efforts of non-Federal landowners who are contributing to the enhancement of essential habitat features for listed species through exclusion of their lands from a critical habitat designation. The jeopardy standard of section 7 of the Act will continue to provide protection to listed species in these areas when there is a Federal nexus.

V. Queen Emma Foundation Lands

Queen Emma Foundation owns and manages 475 ac (192 ha) in two parcels in Unit 54: one is 384 ac (155 ha), and the other is 91 ac (37 ha). The 91-ac (37-ha) parcel overlaps existing designated critical habitat for the federally endangered picture-wing fly, *Drosophila ochrobasis* (see *Drosophila ochrobasis*—Unit 4—Kohala Mountains West at 50 CFR 17.95(i) and 73 FR 73795, December 4, 2008). In our March 29, 2023, proposed rule (88 FR 18756), we stated that we were considering these parcels for exclusion from this final critical habitat designation. For the purposes of distinguishing between these two Unit 54 parcels in our balancing analysis below, we hereafter refer to the 91-ac (37-ha) parcel that overlaps designated critical habitat for *Drosophila ochrobasis* as the ''*D. ochrobasis* parcel,'' and the remaining

384-ac (155-ha) parcel of Unit 54 simply as the ''Unit 54 parcel.''

Conservation and management activities on Queen Emma Foundation lands in the Unit 54 parcel include those associated with the Kohala Watershed Partnership (see ''*b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan*'' *under I. Watershed Partnerships,* above) and the Pelekane Bay Watershed Restoration Project. The goal of this management plan and partnership is to improve the Kohala watershed's condition, and stewardship actions taken to achieve this goal include fencing to reduce feral ungulates, improving groundcover vegetation, and restoring native riparian forest and shrubland. Conservation measures of Queen Emma Foundation, through the Pelekane Bay Watershed Restoration Project and the Kohala Watershed Partnership, benefit habitat for all species in the Unit 54 parcel, including *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.* While the *D. ochrobasis* parcel would otherwise benefit from these same conservation measures, most management activities do not occur in the *D. ochrobasis* parcel because these 91 acres (37 ha) are made up of gulch areas with steep terrain which make the conservation activities that occur throughout the rest of Unit 54 impractical here.

Based on Queen Emma Foundation management and participation in the Kohala Watershed Partnership, we evaluated the two parcels of land owned by Queen Emma Foundation and considered for exclusion two parcels (384 ac (155 ha) in the Unit 54 parcel and 91 ac (37 ha) in the *D. ochrobasis* parcel) in Unit 54 separately, to determine if excluding those lands from the final critical habitat designation is appropriate.

Benefits of Inclusion—Queen Emma Foundation

As described above under ''Benefits of Inclusion—Parker Ranch,'' the principal benefit of including an area in critical habitat designation is the requirement of Federal agencies to consult with the Service on actions that may affect the critical habitat. This allows the Service to assess whether Federal actions authorized, funded, or carried out are likely to result in the destruction or adverse modification of designated critical habitat and, if so, to identify alternatives to avoid that result; this is in addition to assessing whether the Federal action is likely to jeopardize the listed species. Thus, critical habitat designation may provide greater benefits to the species than the listing would alone. Therefore, critical habitat designation may provide a regulatory benefit for *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* on lands owned by Queen Emma Foundation in the Unit 54 parcel and the *D. ochrobasis* parcel.

Another possible benefit of including lands in critical habitat is public education regarding the potential conservation value of an area that may help focus conservation efforts on areas of high conservation value for certain species. We consider any information about *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats that reaches a wide audience, including parties engaged in conservation activities, to be valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of the species in these units.

Therefore, because activities with a Federal nexus will require section 7 consultation, and because of the occurrence of these species on Queen Emma Foundation lands, it is expected that there may be some, but limited, benefits from including the Unit 54 parcel and the *D. ochrobasis* parcel of Queen Emma Foundation lands in the critical habitat designation. The principal benefit of any designated critical habitat is that activities in and affecting such habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid destruction or adverse modification of critical habitat.

Benefits of Exclusion—Queen Emma Foundation

The benefits of excluding the 384-ac (155-ha) Unit 54 parcel owned by Queen Emma Foundation from this designation of critical habitat include: (1) the continued implementation of conservation plans (Kohala Mountain Watershed Management Plan) that include actions that benefit *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae;* (2) strengthening of our effective partnership with Queen Emma Foundation and other neighboring landowners to promote voluntary, proactive conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats; (3) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation efforts that might not otherwise occur; and (4) encouragement of developing and implementing conservation and management plans in the future for these species or other federally listed and sensitive species.

In some cases, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1,265; Bean 1998, p. 10706). The magnitude of this negative outcome is amplified in situations where active management measures (such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 1998, pp. 10706–10708). We find that the exclusion of these specific areas of non-federally owned lands from this critical habitat designation can contribute to the species' recovery and provide a superior level of conservation than critical habitat designation can provide alone. We have also found that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 1998, entire). Additionally, partnerships with non-Federal landowners are vital to the conservation of these species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions.

Excluding the 384-ac (155-ha) Unit 54 parcel of land owned and managed by Kahua Ranch from critical habitat will help foster the partnerships the landowners and land managers have developed with Federal and State agencies and local conservation organizations, will encourage the continued implementation of voluntary conservation actions for the benefit of the species and their habitats on these lands, and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive

effect of excluding from critical habitat areas managed by active conservation partners to be a significant benefit of exclusion.

The benefits of excluding the *D. ochrobasis* parcel (91 ac (37 ha)) owned by Queen Emma Foundation from this designation of critical habitat are similar to those of the Unit 54 parcel, but to a lesser degree because most of the conservation management actions prescribed under the Kohala Mountain Watershed Management Plan are not implemented on the *D. ochrobasis* parcel. Even though the *D. ochrobasis* parcel and the Unit 54 parcel are both covered under the Kohala Mountain Watershed Management Plan, the steep terrain of the gulch areas that make up the *D. ochrobasis* parcel would make the actual implementation of conservation actions challenging, and would likely require specialized equipment to stablize gulch slopes and soils. As a result, most of the management activities associated with the Kohala Mountain Watershed Management Plan that the Queen Emma Foundation carries out throughout the rest of Unit 54 are not implemented in these 91 ac (37 ha) of steep gulch habitat. Therefore, the benefits of exclusion of the *D. ochrobasis* parcel are limited mostly to the potential to encourage effective partnerships with Queen Emma Foundation and other neighboring landowners.

Benefits of Exclusion Outweigh the Benefits of Inclusion—Queen Emma Foundation, the Unit 54 Parcel

We evaluated the approximately 384-ac (155-ha) parcel owned by Queen Emma Foundation in Unit 54 for exclusion from this designation of critical habitat. We determined the benefits of excluding the Unit 54 parcel lands outweigh the benefits of including them as critical habitat in this designation. We conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small because of the limited distinction between actions to avoid jeopardy and adverse modification. While Queen Emma Foundation may receive Federal grants (actions which carry a Federal nexus) occasionally, all areas of Queen Emma Foundation lands being evaluated are occupied by one or more of the 12 species addressed in this final rule. Therefore, the few section 7 consultations that may occur will include a jeopardy analysis, as described above, and conservation measures that apply to a jeopardy analysis are expected to be similar to those that apply to an adverse modification analysis. These marginal regulatory benefits are further reduced by the existence of conservation plans and implemented actions in the Unit 54 parcel, which include habitat conservation that addresses the special management considerations. Furthermore, the potential educational and informational benefits of critical habitat designation on areas containing the physical and biological features essential to the conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* would be minimal in the Unit 54 parcel because the landowner has demonstrated their knowledge of the species and their habitat needs in the process of developing conservation partnerships with the Service and others.

In contrast, the benefits derived from excluding the Unit 54 parcel lands owned by Queen Emma Foundation and enhancing our partnership with this landowner are significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in Hawaii, a State with relatively little Federal land ownership but many species of conservation concern. Excluding the Unit 54 parcel from critical habitat will help foster the partnerships the landowners and land managers in question have developed with Federal and State agencies and local conservation organizations and will encourage the continued implementation of voluntary conservation actions for the benefit of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* and their habitats on these lands.

The current active conservation efforts on Queen Emma Foundation lands in the Unit 54 parcel benefit these species, satisfying factor (vi) of the section 4(b)(2) exclusion analysis, as described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The partnership and management plan are longstanding and have demonstrated implementation and success, and we have a reasonable expectation that the conservation management strategies or actions in the plans will be implemented, satisfying factors (v) and (vii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The Kohala Mountain Watershed Management Plan includes multiple objectives that satisfy factor (viii), described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' by promoting monitoring and adaptive management to ensure conservation measures are effective. In addition, this partnership not only provides a benefit for the conservation of these species but may also serve as a model and aid in fostering future cooperative relationships with other parties in these areas of Hawai'i and in other locations for the benefit of other endangered or threatened species.

Management by Queen Emma Foundation through participation in the Kohala Mountain Watershed Management Plan and the Kohala Watershed Partnership provides significant habitat protection for *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae.* We find that excluding the Unit 54 parcel from critical habitat which is under a long-term conservation and management plan to protect the habitats that support these species, will preserve our partnership with the Queen Emma Foundation in the State of Hawaii and will encourage future collaboration towards conservation and recovery of listed species. In summary, the partnership benefits to the subject species in the Unit 54 parcel outweigh the small potential regulatory, educational, and ancillary benefits of including the Unit 54 parcel in this final critical habitat designation.

Benefits of Inclusion Outweigh the Benefits of Exclusion—Queen Emma Foundation, the *D. ochrobasis* Parcel

We evaluated the approximately 91-ac (37-ha) *D. ochrobasis* parcel owned by Queen Emma Foundation in Unit 54 for exclusion from this designation of critical habitat. We determined the benefits of including these lands outweigh the benefits of excluding them as critical habitat in this designation. We conclude that the additional regulatory and educational benefits of including the *D. ochrobasis* parcel as critical habitat outweigh the benefit afforded by the Kohala Mountain Watershed Management Plan, because most management activities under this plan cannot be carried out in this area due to practical concerns. Furthermore, the potential educational and informational benefits of critical habitat

designation on areas containing the physical and biological features essential to the conservation of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae* within the riparian and gulch areas of the *D. ochrobasis* parcel would be relatively significant. In contrast, the benefits derived from excluding the lands owned by Queen Emma Foundation in the *D. ochrobasis* parcel would be limited to potentially enhancing partnerships. In addition, we held discussions with the Queen Emma Foundation regarding their land management activities in Unit 54 during the public comment period that followed our March 29, 2023, proposed rule (88 FR 18756). They confirmed at that time that the steep gulches that make up the 91 ac of the *D. ochrobasis* parcel restrict implementation of most of the habitat management activities that they perform on the rest of their lands in Unit 54, and they were amenable to those 91 ac being part of the critical habitat designation rather than excluded with the remaining 384 ac. In summary, we conclude that though minor, the potential regulatory, educational, and ancillary benefits of including the *D. ochrobasis* parcel in this final critical habitat designation outweigh the limited potential to enhance partnerships.

Exclusion Will Not Result in Extinction of the Species—Queen Emma Foundation, the Unit 54 Parcel

We determined that the exclusion of approximately 384 ac (155 ha) in the Unit 54 parcel owned by Queen Emma Foundation from this designation of critical habitat will not result in the extinction of *Cyanea tritomantha, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei,* or *Stenogyne cranwelliae.* Protections afforded to these species based on their listed status, and afforded to their habitats by the management and conservation plans, provide assurances that these species will not go extinct as a result of excluding these lands from the critical habitat designation.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that a critical habitat designation does not necessarily require affirmative action to restore or actively manage critical habitat for the benefit of listed species; the regulatory effect of critical habitat is that Federal agencies must ensure (though consultation with the Service) that any activity they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. It is, therefore, advantageous for the conservation of these species to support the proactive efforts of non-Federal landowners who are contributing to the enhancement of essential habitat features for listed species through exclusion of their lands from a critical habitat designation. The jeopardy standard of section 7 of the Act will continue to provide protection to listed species in these areas when there is a Federal nexus.

VI. Kamehameha Schools Lands

Kamehameha Schools manages five parcels of land (155 ac (63 ha), 33 ac (13 ha), 176 ac (71 ha), 647 ac (262 ha), and 93 ac (38 ha)) in Units 52, 53, 54, 44, and 51, respectively. These parcels were identified as lands we were considering for exclusion in our March 29, 2023, proposed rule (88 FR 18756). As stated in table 3, the boundaries for *Drosophila digressa*—Units 1 and 2 are identical to Section 1 (plant Unit 52) and Section 11 (plant Unit 51), respectively.

Conservation and management activities on Kamehameha Schools lands in Units 52, 53, 54, 44, and 51, as well as *Drosophila digressa*—Units 1 and 2, include activities associated with Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program Units 52, 53, 54, 44, 51, 1, and 2; Mauna Kea Watershed Alliance Units 52 and 1; Mauna Kea Watershed Management Plan Units 52 and 1; Kohala Watershed Partnership Units 53 and 54; Kohala Mountain Watershed Management Plan Units 53 and 54; the Three Mountain Alliance Management Plan Units 44, 51, and 2; and Safe Harbor Agreement Trustees of the Estate of Bernice P. Bishop, Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement Units 51 and 2 (see, above, *Safe Harbor Agreement Trustees of the Estate of Bernice P. Bishop, DBA, Kamehameha Schools Keauhou and Kīlauea Forest Lands Hawai'i Island, Hawai'i (Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement), June 2017* under ''Private or Other Non-Federal Conservation Plans Related to Permits Under Section 10 of the Act''; ''a. Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan,'' ''b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan,'' and ''c. Three Mountain Alliance Watershed Partnership and the Three Mountain Alliance Management Plan'' under I. *Watershed Partnerships* in ''Non-Permitted Conservation Plans, Agreements, or Partnerships''; and ''b. Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program'' under II. *Other Partnerships* in ''Non-Permitted Conservation Plans, Agreements, or Partnerships''). Conservation measures of Kamehameha Schools, through its Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program, benefit habitat for all species within Units 52, 53, 54, 44, and 51, as well as *Drosophila digressa*—Units 1 and 2, including *Bidens hillebrandiana* ssp. *hillebrandiana* (Unit 53), *Cyanea tritomantha* (Units 52, 54, 44, and 51), *Cyrtandra wagneri* (Unit 52), *Melicope remyi* (Units 52 and 54), *Phyllostegia floribunda* (Units 52, 54, and 51), *Pittosporum hawaiiense* (Units 52, 54, 44, and 51), *Schiedea diffusa* ssp. *macraei* (Units 52, 54, 44, and 51), *Stenogyne cranwelliae* (Units 52, 54, 44, and 51), and *Drosophila digressa* (Units 1 and 2). In total, Kamehameha Schools owns and manages 1,104 ac (447 ha) of lands that were proposed as critical habitat for 9 of the 12 species that are the subjects of this critical habitat designation. Of these lands owned by Kamehameha Schools, 155 ac (63 ha) are within Section 1 and *Drosophila digressa*—Unit 1; 33 ac (13 ha) are within Section 2; 176 ac (71 ha) are within Section 3; 647 ac (262 ha) are within Section 8; and 93 ac (38 ha) are within Section 11 and *Drosophila digressa*—Unit 2.

Conservation management activities on all 1,104 ac (447 ha) of these lands include those associated with the Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program, described below. On the 155 ac (63 ha) within Section 1 and *Drosophila digressa*—Unit 1, conservation management activities also include those associated with the Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan (see ''a. Mauna Kea Watershed Alliance and the Mauna Kea Watershed Management Plan'' under I. *Watershed Partnerships* in ''Non-Permitted Conservation Plans, Agreements, or Partnerships,'' above). On the 209 ac (85 ha) within Sections 2 and 3, conservation management activities also include those associated with the Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan (see ''b. Kohala Watershed Partnership and the Kohala Mountain Watershed Management Plan'' under I. *Watershed Partnerships* in ''Non-Permitted Conservation Plans, Agreements, or Partnerships,'' above). On the 740 ac (299 ha) within Sections 8 and 11 and *Drosophila digressa*—Unit

2, conservation management activities also include those associated with the Three Mountain Alliance Watershed Partnership and the Three Mountain Alliance Management Plan (see ''c. Three Mountain Alliance Watershed Partnership and the Three Mountain Alliance Management Plan'' under I. *Watershed Partnerships* in ''Non-Permitted Conservation Plans, Agreements, or Partnerships,'' above). The 93 ac (38 ha) within Section 11 and *Drosophila digressa*—Unit 2 are also covered by the Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement, described above under ''Private or Other Non-Federal Conservation Plans Related to Permits Under Section 10 of the Act.''

The conservation actions of Kamehameha Schools benefit habitat for *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* by promoting forest regeneration, which increases soil-water retention capacity and improves ecosystem resilience to drying climate conditions; controlling feral ungulates, which reduces trampling of and predation on these plants, including the host plants of *Drosophila digressa;* and controlling weeds, which improves recruitment of native trees, including those that host *Drosophila digressa* and support habitat for these species. Kamehameha Schools also takes actions that reduce the incidence of fire, which benefits forest habitat for these species by minimizing wildland fire risk.

Based on Kamehameha Schools' management; Kamehameha Schools ʻĀina Pauahi Natural Resources Management Program; and participation in the Mauna Kea Watershed Alliance, Mauna Kea Watershed Management Plan, Kohala Watershed Partnership, the Kohala Mountain Watershed Management Plan, the Three Mountain Alliance Management Plan, and the Safe Harbor Agreement Trustees of the Estate of Bernice P. Bishop (Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement), we evaluated the following lands owned by Kamehameha Schools and considered for exclusion to determine if excluding these lands from the final critical habitat designation is appropriate: 155 ac (63 ha), 33 ac (13 ha), 176 ac (71 ha), 647 ac (262 ha), and 93 ac (38 ha) in Units 52, 53, 54, 44, and 51, respectively, and *Drosophila digressa*—Unit 1 (155 ac (63 ha)) and Unit 2 (92 ac (37 ha)).

Benefits of Inclusion—Kamehameha Schools

As described above under ''Benefits of Inclusion—Parker Ranch,'' the principal benefit of including an area in critical habitat designation is the requirement of Federal agencies to consult with the Service on actions that may affect the critical habitat. This allows the Service to assess whether Federal actions authorized, funded, or carried out are likely to result in the destruction or adverse modification of designated critical habitat and, if so, to identify alternatives to avoid that result; this is in addition to assessing whether the Federal action is likely to jeopardize the listed species. Thus, critical habitat designation may provide greater benefits to the species than the listing would alone. Therefore, critical habitat designation may provide a regulatory benefit for *Bidens hillebrandiana* ssp. *hillebrandiana* (Unit 53), *Cyanea tritomantha* (Units 52, 54, 44, and 51) , *Cyrtandra wagneri* (Unit 52), *Melicope remyi* (Units 52 and 54), *Phyllostegia floribunda* (Units 52, 54, and 51), *Pittosporum hawaiiense* Units (52, 54, 44, and 51), *Schiedea diffusa* ssp. *macraei* (Units 52, 54, 44, and 51), *Stenogyne cranwelliae* (Units 52, 54, 44, and 51), and *Drosophila digressa* (Units 1 and 2) on lands owned by Kamehameha Schools in Units 52, 53, 54, 44, and 51, and *Drosophila digressa*—Units 1 and 2.

Another possible benefit is that the designation of critical habitat can serve to educate the landowner and public regarding the potential conservation value of an area, and this may focus and contribute to conservation efforts by other parties by clearly delineating areas of high conservation value for certain species. Due to the reliance of these species on the remaining coastal, mesic forest, wet forest, and wet grassland and shrubland ecosystems, the relative importance of these parcels to the species is high, and any information about these nine species and their habitats that reaches a wide audience, including other parties engaged in conservation activities, would be considered valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of the species in these units.

Therefore, because activities with a Federal nexus will require section 7 consultation, and because of the occurrence of these species on Kamehameha Schools lands, it is expected that there may be some, but limited, benefits from including Kamehameha Schools land in this final critical habitat designation. The principal benefit of any designated critical habitat is that activities occurring in or affecting such habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid destruction or adverse modification of critical habitat.

Benefits of Exclusion—Kamehameha Schools

The benefits of excluding the five parcels (155 ac (63 ha), 33 ac (13 ha), 176 ac (71 ha), 647 ac (262 ha), and 93 ac (38 ha) in Units 52, 53, 54, 44, and 51, respectively, and *Drosophila digressa* Units 1 (155 ac (63 ha)) and 2 (92 ac (37 ha))) owned by Kamehameha Schools from this designation of critical habitat include: (1) the continued implementation of conservation plans (ʻĀina Pauahi Natural Resources Management Program, the Mauna Kea Watershed Management Plan, the Kohala Mountain Watershed Management Plan, the Three Mountain Alliance Management Plan, and the Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement) that include actions that benefit *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa;* (2) strengthening of our effective partnership with Kamehameha Schools and other neighboring landowners to promote voluntary, proactive conservation of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa* and their habitats; (3) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation benefits that might not otherwise occur; and (4) encouragement of developing and implementing conservation and management plans in the future for these species or other federally listed and sensitive species.

In some cases, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1,265; Bean 1998, p. 10706). The magnitude of this negative outcome is amplified in situations where active management measures

(such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 1998, pp. 10706–10708). We find that the exclusion of these specific areas of non-federally owned lands from this critical habitat designation can contribute to the species' recovery and provide a superior level of conservation than critical habitat designation can provide alone. We have also found that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 1998, entire). Additionally, partnerships with non-Federal landowners are vital to the conservation of these species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions.

Excluding lands owned and managed by Kamehameha Schools in plant Units 52, 53, 54, 44, 51, and *Drosophila digressa* Units 1 and 2 from critical habitat will help foster the partnerships the landowners and land managers have developed with Federal and State agencies and local conservation organizations, will encourage the continued implementation of voluntary conservation actions for the benefit of the species and their habitats on these lands, and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive effect of excluding from critical habitat areas managed by active conservation partners to be a significant benefit of exclusion.

Benefits of Exclusion Outweigh the Benefits of Inclusion—Kamehameha Schools

We evaluated approximately 1,104 ac (447 ha) of lands in Units 52, 53, 54, 44, 51, and *Drosophila digressa* Units 1 and 2, owned by Kamehameha Schools for exclusion from this designation of critical habitat. We determined the benefits of excluding these lands outweigh the benefits of including them as critical habitat for the subject species on Hawai'i Island. We conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small because of the limited distinction between actions to avoid jeopardy and adverse modification. While Kamehameha Schools may receive Federal grants (actions which carry a Federal nexus) from time to time, all areas of Kamehameha Schools lands being evaluated are occupied by one or more of the 12 species addressed in this final rule. Therefore, the few section 7 consultations that may occur will include a jeopardy analysis, as described above, and conservation measures that apply to a jeopardy analysis and an adverse modification analysis are expected to be similar. These marginal regulatory benefits are further reduced by the existence of conservation plans and implemented actions, which include habitat conservation that addresses the special management considerations. Kamehameha Schools' ʻĀina Pauahi Natural Resources Management Program includes the protection and conservation of natural resources, water resources, and ancestral places (Kamehameha Schools 2022, entire). Furthermore, the potential educational and informational benefits of critical habitat designation on areas containing the physical and biological features essential to the conservation of *Bidens hillebrandiana* ssp. *hillebrandiana* (Unit 53), *Cyanea tritomantha* (Units 52, 54, 44, and 51), *Cyrtandra wagneri* (Unit 52), *Melicope remyi* (Units 52 and 54), *Phyllostegia floribunda* (Units 52, 54, and 51), *Pittosporum hawaiiense* (Units 52, 54, 44, and 51), *Schiedea diffusa* ssp. *macraei* (Units 52, 54, 44, and 51), *Stenogyne cranwelliae* (Units 52, 54, 44, and 51), and *Drosophila digressa* (Units 1 and 2) would be minimal because the landowner has demonstrated their knowledge of the species and their habitat needs in the process of developing conservation partnerships with the Service and others.

In contrast, the benefits derived from excluding the lands owned by Kamehameha Schools and enhancing our partnership with this landowner is significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in Hawaii, a State with relatively little Federal land ownership but many species of conservation concern. Excluding these areas from critical habitat will help foster the partnerships the landowners and land managers in question have developed with Federal and State agencies and local conservation organizations and will encourage the continued implementation of voluntary conservation actions for the benefit of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae* and *Drosophila digressa* and their habitats on these lands.

The current active conservation efforts on Kamehameha Schools lands in Units 52, 53, 54, 44, 51 and *Drosophila digressa* Units 1 and 2 benefit these species, satisfying factor (vi) of the section 4(b)(2) exclusion analysis, as described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The partnerships and management plans are longstanding and have demonstrated implementation and success, and we have a reasonable expectation that the conservation management strategies or actions in the plans will be implemented, satisfying factors (v) and (vii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships.'' The Kamehameha Schools' ʻĀina Pauahi Natural Resources Management Program, the Mauna Kea Watershed Management Plan, the Kohala Mountain Watershed Management Plan, the Three Mountain Alliance Management Plan, and the Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor Agreement include multiple objectives that satisfy factor (viii) described above under ''Non-Permitted Conservation Plans, Agreements, or Partnerships'' by promoting monitoring and adaptive management to ensure conservation measures are effective. Kamehameha Schools established a sustainable stewardship policy to guide the use of its lands. In addition, these partnerships not only provide a benefit for the conservation of these species but may also serve as a model and aid in fostering future cooperative relationships with other parties in these areas of Hawai'i and in other locations for the benefit of other endangered or threatened species.

Management by Kamehameha Schools through participation in the Mauna Kea Watershed Management Plan, the Kohala Mountain Watershed Management Plan, the Three Mountain Alliance Management Plan, and implementation of the ʻĀina Pauahi Natural Resources Management Program and the Kamehameha Schools Keauhou and Kīlauea Forest Lands Safe Harbor

Agreement provides significant habitat protection for *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* and *Drosophila digressa.* We find that excluding areas from critical habitat that are under long-term conservation and management plans to protect the habitat that supports these species will preserve our partnership with the Kamehameha Schools in the State of Hawaii and will encourage future collaboration toward conservation and recovery of listed species. In summary, these partnership benefits to the subject species outweigh the small potential regulatory, educational, and ancillary benefits of including the Kamehameha Schools land in this final critical habitat designation.

Exclusion Will Not Result in Extinction of the Species—Kamehameha Schools

We determined that the exclusion of approximately 155 ac (63 ha), 33 ac (13 ha), 176 ac (71 ha), 647 ac (262 ha), and 93 ac (38 ha) in Units 52, 53, 54, 44, and 51, respectively, and *Drosophila digressa* Units 1 (155 ac (63 ha)) and 2 (92 ac (37 ha)) owned by Kamehameha Schools from this designation of critical habitat will not result in the extinction of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Melicope remyi, Phyllostegia floribunda, Pittosporum hawaiiense, Schiedea diffusa* ssp. *macraei, Stenogyne cranwelliae,* or *Drosophila digressa.* Protections afforded to these species based on their listed status, and afforded to their habitats by the management and conservation plans, provide assurances that these species will not go extinct as a result of excluding these lands from the critical habitat designation. While some mitigation measures in the SHA are still underway, the primary habitat management and restoration goals established for these parcels under the SHA and other conservation management plans are being implemented, and Kamehameha Schools are in compliance with the terms and conditions of the SHA. Kamehameha Schools is fully aware of the importance of the ecosystems that provide the habitat for these nine species for which critical habitat was proposed on their lands and their organization routinely provides public education on these topics.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that a critical habitat designation does not necessarily require affirmative actions to restore or actively manage critical habitat for the benefit of listed species; the regulatory effect of critical habitat is that Federal agencies must ensure (through consultation with the Service) that any activity they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. It is, therefore, advantageous for the conservation of these species to support the proactive efforts of non-Federal landowners who are contributing to the enhancement of essential habitat features for listed species through exclusion of their lands from a critical habitat designation. The jeopardy standard of section 7 of the Act will continue to provide protection to listed species in these areas when there is a Federal nexus.

Summary of Exclusions

As discussed above, based on the information provided by entities seeking exclusion, as well as any additional public comments we received on our March 29, 2023, proposed rule, we evaluated whether certain lands in the proposed critical habitat were appropriate for exclusion from this final designation pursuant to section 4(b)(2) of the Act. Table 7, below, summarizes the areas we are excluding from this critical habitat designation for the 12 Hawai'i Island species; the table provides approximate areas (ac, ha) of lands excluded from this critical habitat designation. In addition to the acres we evaluated for exclusion that are summarized in Table 7, we also evaluated 91 ac (37 ha) of Queen Emma Foundation land in Unit 54 (the *D. ochrobasis* parcel) for exclusion but did not ultimately exclude them.

TABLE 7—AREAS EXCLUDED FROM CRITICAL HABITAT DESIGNATION BY CRITICAL HABITAT UNIT

Plant section and unit	Drosophila unit	Landowner	Area excluded from critical habitat	
			Acres	Hectares
Section 1, Unit 52	Unit 1	Kamehameha Schools	155	63
Section 1, Unit 52	Unit 1	Parker Ranch Waipunalei, LLC	403	163
Section 2, Unit 53		Kamehameha Schools	33	13
Section 2, Unit 53		Laupāhoehoe Nui	134	54
Section 3, Unit 54		State Department of Hawaiian Home Lands.	36	15
Section 3, Unit 54		Kahua Ranch	605	245
Section 3, Unit 54		Kamehameha Schools	176	71
Section 3, Unit 54		Laupāhoehoe Nui	134	54
Section 3, Unit 54		Parker Ranch Waiemi, LLC	372	151
Section 3, Unit 54		Queen Emma Foundation	384	155
Section 8, Unit 44		Kamehameha Schools	647	262
Section 11, Unit 51	Unit 2	Kamehameha Schools	93	38
Totals			3,172	1,284

Required Determinations

Regulatory Planning and Review (Executive Orders 12866, 13563, and 14094)

Executive Order (E.O.) 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law.

E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

E.O. 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

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

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

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

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

During the development of this final rule, we reviewed and evaluated all information submitted during the comment period on the March 29, 2023, proposed rule (88 FR 18756) that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Based on this information, we affirm our certification that this critical habitat designation will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare statements of energy effects ''to the extent permitted by law'' when undertaking actions identified as significant energy actions (66 FR 28355; May 22, 2001). E.O. 13211 defines a ''significant energy action'' as an action that (i) is a significant regulatory action under E.O. 12866 (or any successor order, including most recently E.O. 14094 (88 FR 21879; April 11, 2023)); and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is not a significant regulatory action under E.O. 12866 or 14094. Therefore, this action is not a significant energy action, and there is no requirement to prepare a statement of energy effects for this action.

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

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

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

The designation of critical habitat does not impose a legally binding duty

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

(2) We do not believe that this rule will significantly or uniquely affect small governments. Small governments will be affected only to the extent that any of their programs receive Federal funds, require Federal permits, or otherwise are a result of federally authorized activities, in which case the Federal agency must ensure that the Federal action will not adversely affect the critical habitat. The majority of the critical habitat units are already managed for natural resource conservation by the Federal Government or the State of Hawaii, and most critical habitat units have co-occurring federally listed species that are already being considered by the State and municipalities as a result of any Federal actions proposed in the area. Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the 12 Hawai'i Island species in a takings implications assessment. The Act does not authorize us to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that this designation of critical habitat for the 12 Hawai'i Island species does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

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

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

Civil Justice Reform—Executive Order 12988

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

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

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

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

Regulations adopted pursuant to section 4(a) of the Act are exempt from the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and do not require an environmental analysis under NEPA. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This includes listing, delisting, and reclassification rules, as well as critical habitat designations. In a line of cases starting with *Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), the courts have upheld this position.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with

federally recognized Tribes on a government-to-government basis. In accordance with Secretaries' Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribal lands fall within the boundaries of the critical habitat designation for the 12 Hawai'i Island species, so no Tribal lands will be affected by this designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Pacific Islands Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

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

Regulation Promulgation

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

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

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

■ 2. In § 17.11, in paragraph (h), amend the table ''List of Endangered and Threatened Wildlife'' by revising the entry for ''Fly, Hawaiian picture-wing (*Drosophila digressa*)'' under ''Insects'' to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
		Insects		
* * *	* * *	* * *	* * *	* * *
Fly, Hawaiian picture-wing	*Drosophila digressa*	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.95(i).[CH]
* * *	* * *	* * *	* * *	* * *

■ 3. In § 17.12, in paragraph (h), amend the table ''List of Endangered and Threatened Plants'' by revising the entries for ''Bidens hillebrandiana ssp. hillebrandiana'', ''Cyanea marksii'', ''Cyanea tritomantha'', ''Cyrtandra nanawaleensis'', ''Cyrtandra wagneri'', ''Melicope remyi'', ''Phyllostegia floribunda'', ''Pittosporum hawaiiense'', ''Schiedea diffusa ssp. macraei'', ''Schiedea hawaiiensis'', and ''Stenogyne cranwelliae'' under ''Flowering Plants'' to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
		Flowering Plants		
* * *	* * *	* * *	* * *	* * *
Bidens hillebrandiana ssp. *hillebrandiana.*	Kookoolau	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* * *	* * *	* * *	* * *	* * *
Cyanea marksii	Haha	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* * *	* * *	* * *	* * *	* * *
Cyanea tritomantha	Aku	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* * *	* * *	* * *	* * *	* * *
Cyrtandra nanawaleensis	Haiwale	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* * *	* * *	* * *	* * *	* * *
Cyrtandra wagneri	Haiwale	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
* *	*	*	*	* *
Melicope remyi	No common name	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* *	*	*	*	* *
Phyllostegia floribunda	No common name	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* *	*	*	*	* *
Pittosporum hawaiiense	Hoawa, haawa	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* *	*	*	*	* *
Schiedea diffusa ssp. *macraei*	No common name	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* *	*	*	*	* *
Schiedea hawaiiensis	Maolioli	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* *	*	*	*	* *
Stenogyne cranwelliae	No common name	Wherever found	E	78 FR 64638, 10/29/2013; 50 CFR 17.99(k).[CH]
* *	*	*	*	* *

■ 4. In § 17.95, amend paragraph (i) by adding an entry for ''Hawaiian picture-wing fly (*Drosophila digressa*)'' following the entry for ''Hawaiian picture-wing fly (*Drosophila differens*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(i) * * *

Hawaiian picture-wing fly (*Drosophila digressa*)

(1) Critical habitat units are depicted for Hawaii County, Hawaii, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of *Drosophila digressa* consist of the following components:

(i) In units 1, 2, 5, 6, 7, 8, and 9, the physical or biological features essential to the conservation of *Drosophila digressa* are the features of the wet forest ecosystem and consist of:

(A) Elevation of less than 7,218 feet (ft) (2,200 meters (m)).

(B) Annual precipitation that is greater than 98 inches (in) (250 centimeters (cm)).

(C) Substrate of very weathered soils to rocky substrate, basaltic lava, undeveloped soils, or developed soils.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

(ii) In unit 3, the physical or biological features essential to the conservation of *Drosophila digressa* are the features of both the wet forest ecosystem and the mesic forest ecosystem and consist of the physical and biological features described in paragraphs (2)(i)(A) through (F) and (2)(iii)(A) through (F) of this entry.

(iii) In unit 4, the physical or biological features essential to the conservation of *Drosophila digressa* are the features of the mesic forest ecosystem and consist of:

(A) Elevation of less than 6,562 ft (2,000 m).

(B) Annual precipitation of 39 to 150 in (100 to 380 cm).

(C) Substrate of rocky, shallow, organic muck soils; rocky talus soils; shallow soils over weathered rock; deep soils over soft weathered rock; or gravelly alluvium.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Charpentiera, Chrysodracon, Metrosideros, Myrsine, Nestegis, Pisonia, Santalum.*

(E) Subcanopy contains one or more of the following native plant genera: *Coprosma, Freycinetia, Leptecophylla, Myoporum, Pipturus, Rubus, Sadleria, Sophora.*

(F) Understory contains one or more of the following native plant genera: *Ctenitis, Doodia, Dryopteris, Pelea, Sadleria.*

(3) Existing humanmade features and structures, such as buildings, aqueducts, runways, roads, and other paved areas, and the land on which they are located existing within the legal boundaries on April 11, 2024, are not included in the critical habitat designation.

(4) Data layers defining map units were created based on summaries of occurrences and landcover layers including habitat characteristics that indicate the physical or biological features essential to the conservation of *Drosophila digressa*. Coordinates were created using World Geodetic System 1984 (WGS84). The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at *https://www.regulations.gov* at Docket No. FWS–R1–ES–2023–0017, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index map follows:

Figure 1 to Hawaiian picture-wing fly (*Drosophila digressa*) paragraph (5)

Critical Habitat for Drosophila digressa

Hawaii Island, HI

Index Map

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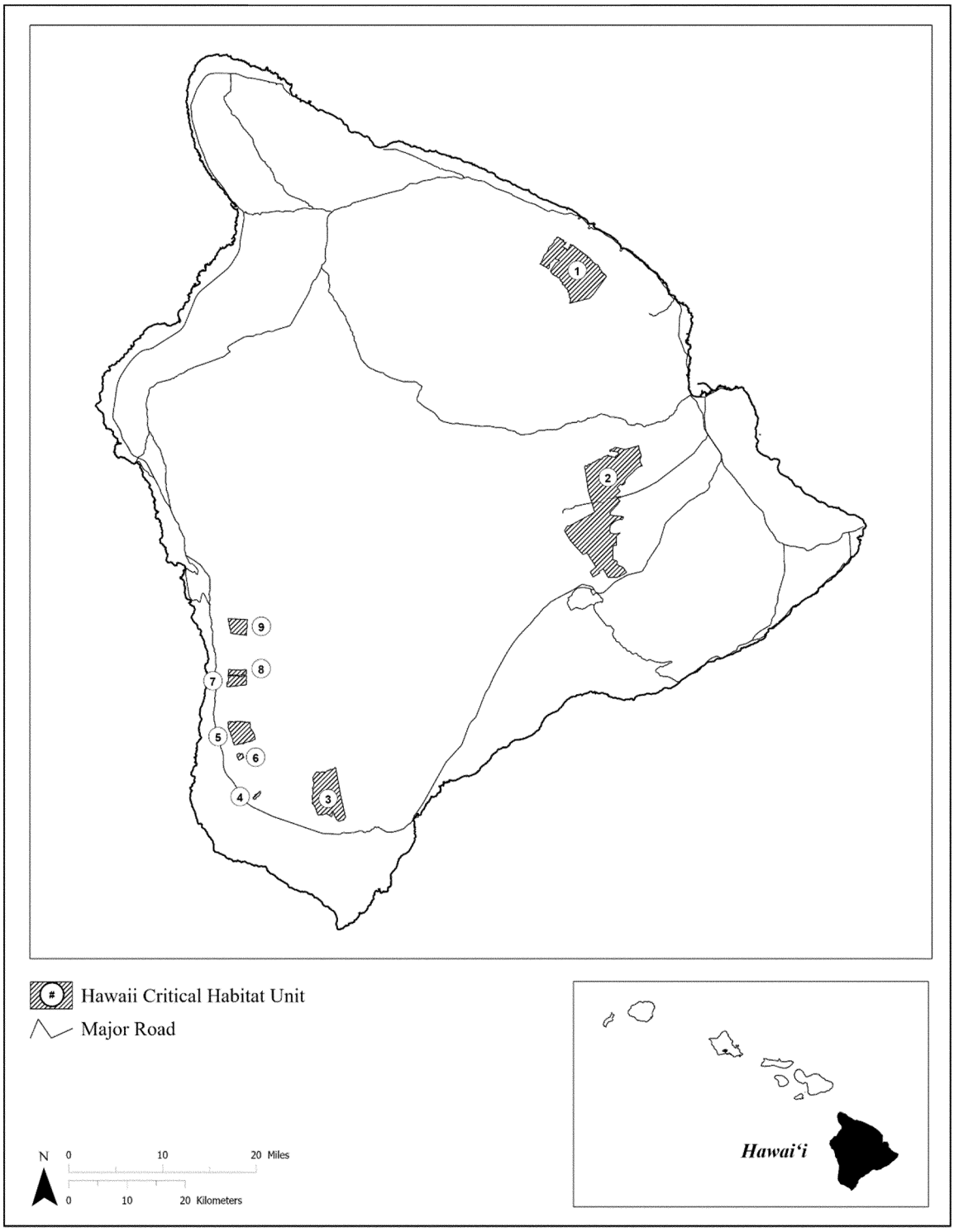


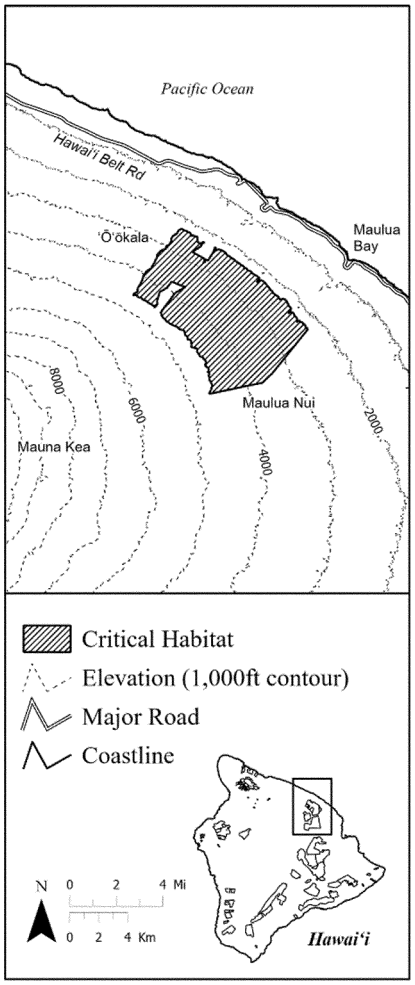
(6) *Drosophila digressa*—Unit 1; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 1 consists of 15,714 ac (6,359 ha) of wet forest ecosystem from Ookala to Maulua Nui on the northeastern slope of Maunakea. Lands within this unit include approximately 4,098 ac (1,658 ha) in Federal ownership, 10,644 ac (4,308 ha) in State ownership, and 972 ac (394 ha) in private or other ownership. Federal lands within this unit are within the Hakalau Forest National Wildlife Refuge Hakalau Forest Unit. State lands within this unit are part of the Hilo Forest Reserve Humuula, Laupahoehoe, and Piha Sections; the Laupahoehoe Natural Area Reserve; and the Manowaialee Forest Reserve.

(ii) Map of *Drosophila digressa*—Unit 1 follows:

Figure 2 to Hawaiian picture-wing fly (*Drosophila digressa*) paragraph (6)(ii)

Critical Habitat for Drosophila digressa
Hawaii Island, HI
Unit 1



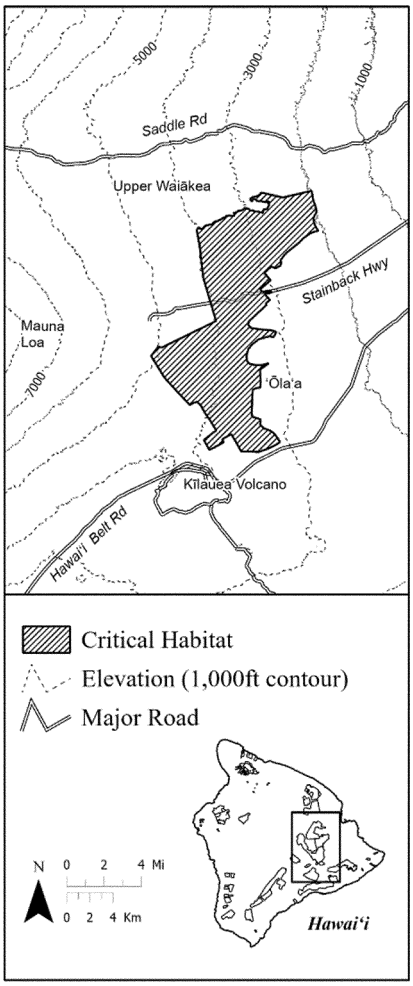
(7) *Drosophila digressa*—Unit 2; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 2 consists of 31,998 ac (12,949 ha) of wet forest ecosystem from Olaa to Upper Waiakea on the eastern slope of Mauna Loa and partially on the northern slope of Kilauea Volcano. Lands within this unit include approximately 7,875 ac (3,187 ha) in Federal ownership, 23,897 ac (9,671 ha) in State ownership, and 226 ac (91 ha) in private or other ownership. Federal lands in this unit are within Hawaii Volcanoes National Park. State lands in this unit are part of the Hilo Forest Reserve Kukuau Section, Olaa Forest Reserve Mountain View Section, Upper Waiākea Forest Reserve, Waiākea Forest Reserve, Puu Makaala Natural Area Reserve, and Waiakea 1942 Lava Flow Natural Area Reserve.

(ii) Map of *Drosophila digressa*—Unit 2 follows:

Figure 3 to Hawaiian picture-wing fly (*Drosophila digressa*) paragraph (7)(ii)

Critical Habitat for Drosophila digressa
Hawaii Island, HI
Unit 2



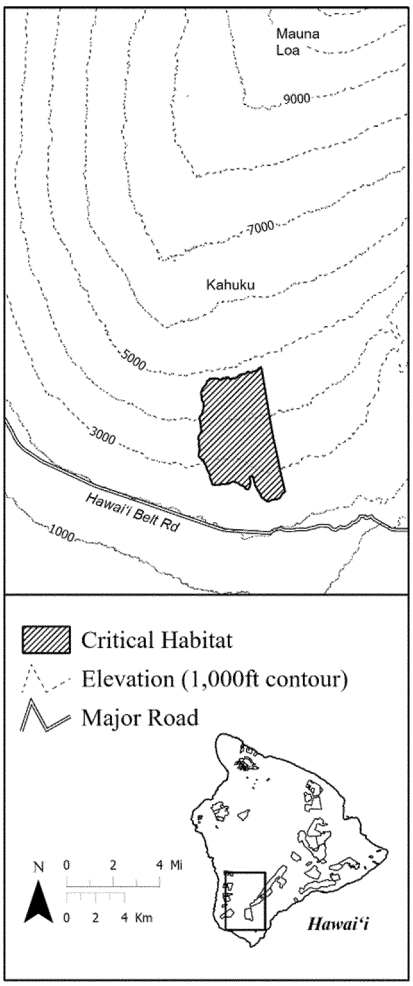
(8) *Drosophila digressa*—Unit 3; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 3 consists of 8,781 ac (3,554 ha) of wet and mesic forest ecosystems at Kahuku on the southern slopes of Mauna Loa. Lands within this unit include approximately 8,773 ac (3,550 ha) in Federal ownership and 8 ac (3 ha) in State ownership. Federal lands within this unit are within Hawaii Volcanoes National Park. State-owned lands in this unit are part of the Ka'ū Forest Reserve.

(ii) Map of *Drosophila digressa*—Unit 3 follows:

Figure 4 to Hawaiian picture-wing fly (*Drosophila digressa*) paragraph (8)(ii)

Critical Habitat for Drosophila digressa
Hawaii Island, HI
Unit 3



(9) *Drosophila digressa*—Unit 4; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 4 consists of 167 ac (67 ha) of mesic forest ecosystem at Manuka on the southern slopes of Mauna Loa. Lands within this unit are entirely in State ownership and are part of the Manuka Natural Area Reserve.

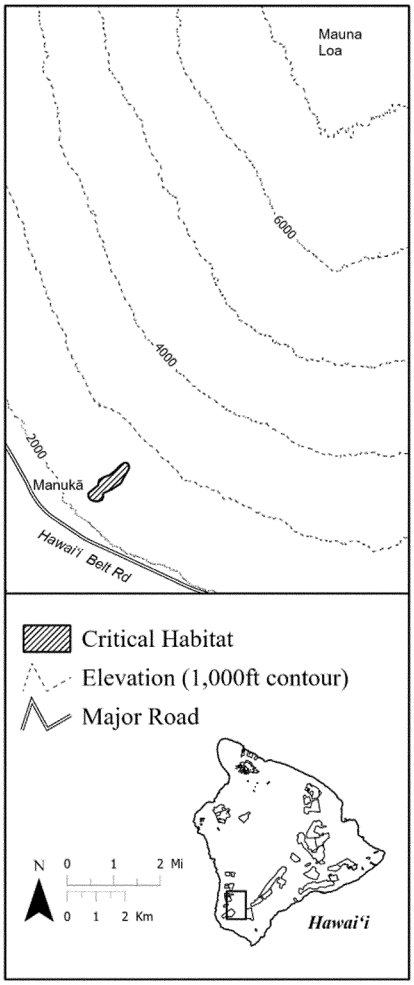
(ii) Map of *Drosophila digressa*—Unit 4 follows:

Figure 5 to Hawaiian picture-wing fly (*Drosophila digressa*) paragraph (9)(ii)

Critical Habitat for Drosophila digressa

Hawaii Island, HI

Unit 4



(10) *Drosophila digressa*—Unit 5; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 5 consists of 3,412 ac (1,381 ha) of wet forest ecosystem from Kipahoehoe to Honomalino on the southwestern slopes of Mauna Loa. Lands within this unit include approximately 411 ac (166 ha) in State ownership and 3,001 ac (1,214 ha) in private or other ownership. State-owned lands in this unit are part of the Kipahoehoe Natural Area Reserve and South Kona Forest Reserve Kapua-Manukā Section. Some private lands are owned by The Nature Conservancy, within the Kona Hema Preserve.

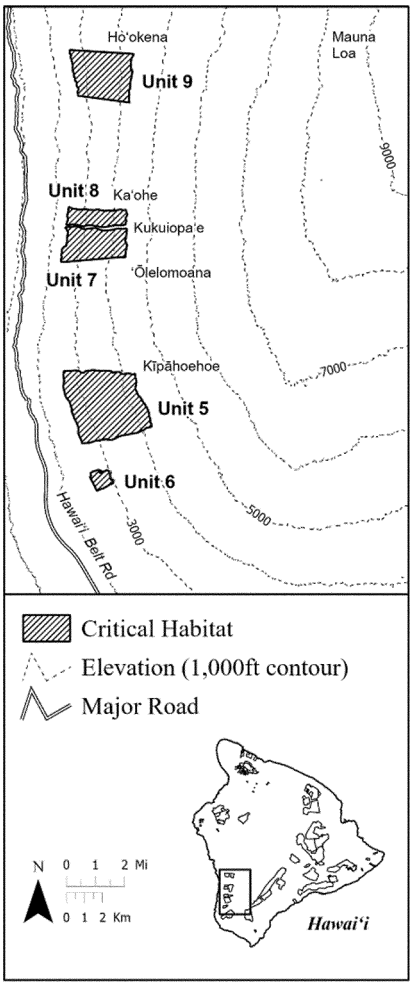
(ii) Map of *Drosophila digressa*—Unit 5, *Drosophila digressa*—Unit 6, *Drosophila digressa*—Unit 7, *Drosophila digressa*—Unit 8, and *Drosophila digressa*—Unit 9 follows:

Figure 6 to Hawaiian picture-wing fly (*Drosophila digressa*) paragraph (10)(ii)

Critical Habitat for Drosophila digressa

Hawaii Island, HI

Unit 5, Unit 6, Unit 7, Unit 8, and Unit 9



(11) *Drosophila digressa*—Unit 6; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 6 consists of 224 ac (91 ha) of wet forest ecosystem from Milolii to Honomalino on the southwestern slopes of Mauna Loa. Lands within this unit are entirely in State ownership and are part of the South Kona Forest Reserve Kapua-Manuka Section.

(ii) Map of *Drosophila digressa*—Unit 6 is provided at paragraph (10)(ii) of this entry.

(12) *Drosophila digressa*—Unit 7; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 7 consists of 1,346 ac (545 ha) of wet forest ecosystem from Kukuiopae to Olelomoana on the southwestern slopes of Mauna Loa. Lands within this unit include approximately 1,179 ac (477 ha) in State ownership and 167 ac (68 ha) in private or other ownership. State-owned lands in this unit are part of the South Kona Forest Reserve Kukuiopae Section.

(ii) Map of *Drosophila digressa*—Unit 7 is provided at paragraph (10)(ii) of this entry.

(13) *Drosophila digressa*—Unit 8; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 8 consists of 661 ac (267 ha) of wet forest ecosystem in Kaohe on the southwestern slopes of Mauna Loa. Lands within this unit include approximately 352 ac (142 ha) in State ownership and 309 ac (125 ha) in private or other ownership. State-owned lands in this unit are part of the South Kona Forest Reserve, Kaohe Section and Kukuiopae Section.

(ii) Map of *Drosophila digressa*—Unit 8 is provided at paragraph (10)(ii) of this entry.

(14) *Drosophila digressa*—Unit 9; Hawaii County, Hawaii.

(i) *Drosophila digressa*—Unit 9 consists of 1,906 ac (771 ha) of wet forest ecosystem in Hookena on the southwestern slopes of Mauna Loa. Lands within this unit include 1,906 ac (771 ha) of Federal land within Hakalau Forest National Wildlife Refuge Kona Forest Unit and less than 1 ac (less than 1 ha) of land that is privately owned or has other ownership.

(ii) Map of *Drosophila digressa*—Unit 9 is provided at paragraph (10)(ii) of this entry.

* * * * *

■ 5. Amend § 17.99 by:
■ a. Revising paragraphs (k) introductory text and (k)(1);
■ b. Redesignating paragraphs (k)(115) and (116) as paragraphs (k)(238) and (239), respectively;
■ c. Redesignating paragraphs (k)(12) through (114) as paragraphs (k)(13) through (115), respectively;
■ d. Adding a new paragraph (k)(12);
■ e. Redesignating newly redesignated paragraphs (k)(15) through (115) as paragraphs (k)(18) through (118), respectively;
■ f. Adding new paragraphs (k)(15) through (17);
■ g. Redesignating newly redesignated paragraphs (k)(19) through (118) as paragraphs (k)(22) through (121), respectively;
■ h. Adding new paragraphs (k)(19) through (21);
■ i. Redesignating newly redesignated paragraphs (k)(32) through (121) as paragraphs (k)(33) through (122), respectively;
■ j. Adding a new paragraph (k)(32);
■ k. Redesignating newly redesignated paragraphs (k)(36) through (122) as paragraphs (k)(39) through (125), respectively;
■ l. Adding new paragraphs (k)(36) through (38);

■ m. Redesignating newly redesignated paragraphs (k)(40) through (125) as paragraphs (k)(43) through (128), respectively;
■ n. Adding new paragraphs (k)(40) through (42);
■ o. Redesignating newly redesignated paragraphs (k)(53) through (128) as paragraphs (k)(59) through (134), respectively;
■ p. Adding new paragraphs (k)(53) through (58);
■ q. Redesignating newly redesignated paragraphs (k)(79) through (134) as paragraphs (k)(81) through (136), respectively;
■ r. Adding new paragraphs (k)(79) and (80);
■ s. Redesignating newly redesignated paragraphs (k)(82) through (136) as paragraphs (k)(90) through (144), respectively;
■ t. Adding new paragraphs (k)(82) through (89);
■ u. Redesignating newly redesignated paragraphs (k)(91) through (144) as paragraphs (k)(92) through (145), respectively;
■ v. Adding a new paragraph (k)(91);
■ w. Redesignating newly redesignated paragraphs (k)(93) through (145) as paragraphs (k)(97) through (149), respectively;
■ x. Adding new paragraphs (k)(93) through (96);
■ y. Redesignating newly redesignated paragraphs (k)(110) through (149) as paragraphs (k)(112) through (151), respectively;
■ z. Adding new paragraphs (k)(110) and (111);
■ aa. Redesignating newly redesignated paragraphs (k)(116) through (151) as paragraphs (k)(117) through (152), respectively;
■ bb. Adding new paragraph (k)(116);
■ cc. Redesignating newly redesignated paragraphs (k)(119) through (152) as paragraphs (k)(121) through (154), respectively;
■ dd. Adding new paragraphs (k)(119) and (120);
■ ee. Redesignating newly redesignated paragraphs (k)(122) through (154) as paragraphs (k)(126) through (158), respectively;
■ ff. Adding new paragraphs (k)(122) through (125);
■ gg. Redesignating newly redesignated paragraphs (k)(134) through (158) as paragraphs (k)(136) through (160), respectively;
■ hh. Adding new paragraphs (k)(134) through (135);
■ ii. Redesignating newly redesignated paragraphs (k)(138) through (160) as paragraphs (k)(139) through (161), respectively;
■ jj. Adding a new paragraph (k)(138);
■ kk. Redesignating newly redesignated paragraphs (k)(141) through (161) as paragraphs (k)(145) through (165), respectively;
■ ll. Adding new paragraphs (k)(141) through (144);
■ mm. Redesignating newly redesignated paragraphs (k)(150) through (165) as paragraphs (k)(151) through (166), respectively;
■ nn. Adding a new paragraph (k)(150);
■ oo. Redesignating newly redesignated paragraphs (k)(152) through (166) as paragraphs (k)(153) through (167), respectively;
■ pp. Adding new paragraph (k)(152);
■ qq. Redesignating newly redesignated paragraphs (k)(155) through (167) as paragraphs (k)(156) through (168), respectively;
■ rr. Adding a new paragraph (k)(155);
■ ss. Redesignating newly redesignated paragraphs (k)(157) through (168) as paragraphs (k)(158) through (169), respectively;
■ tt. Adding a new paragraph (k)(157);
■ uu. Redesignating newly redesignated paragraphs (k)(159) through (169) as paragraphs (k)(160) through (170), respectively;
■ vv. Adding a new paragraph (k)(159);
■ ww. Adding new paragraphs (k)(171) through (237);
■ xx. Revising newly redesignated paragraph (k)(238); and
■ yy. In paragraph (l)(1), adding in alphabetical order entries for ''Family Asteraceae: *Bidens hillebrandiana* ssp. *hillebrandiana* (KOOKOOLAU)'', ''Family Campanulaceae: *Cyanea marksii* (HAHA)'', ''Family Campanulaceae: *Cyanea tritomantha* (AKU)'', ''Family Caryophyllaceae: *Schiedea diffusa* ssp. *macraei* (no common name)'', ''Family Caryophyllaceae: *Schiedea hawaiiensis* (MAOLIOLI)'', ''Family Gesneriaceae: *Cyrtandra nanawaleensis* (HAIWALE)'', Family Gesneriaceae: *Cyrtandra wagneri* (HAIWALE)'', ''Family Lamiaceae: *Phyllostegia floribunda* (no common name)'', ''Family Lamiaceae: *Stenogyne cranwelliae* (no common name)'', ''Family Pittosporaceae: *Pittosporum hawaiiense* (HOAWA, HAAWA)'', and ''Family Rutaceae: *Melicope remyi* (no common name)''.

The revisions and additions read as follows:

§ 17.99 Critical habitat; plants on the Hawaiian Islands, HI.

* * * * *

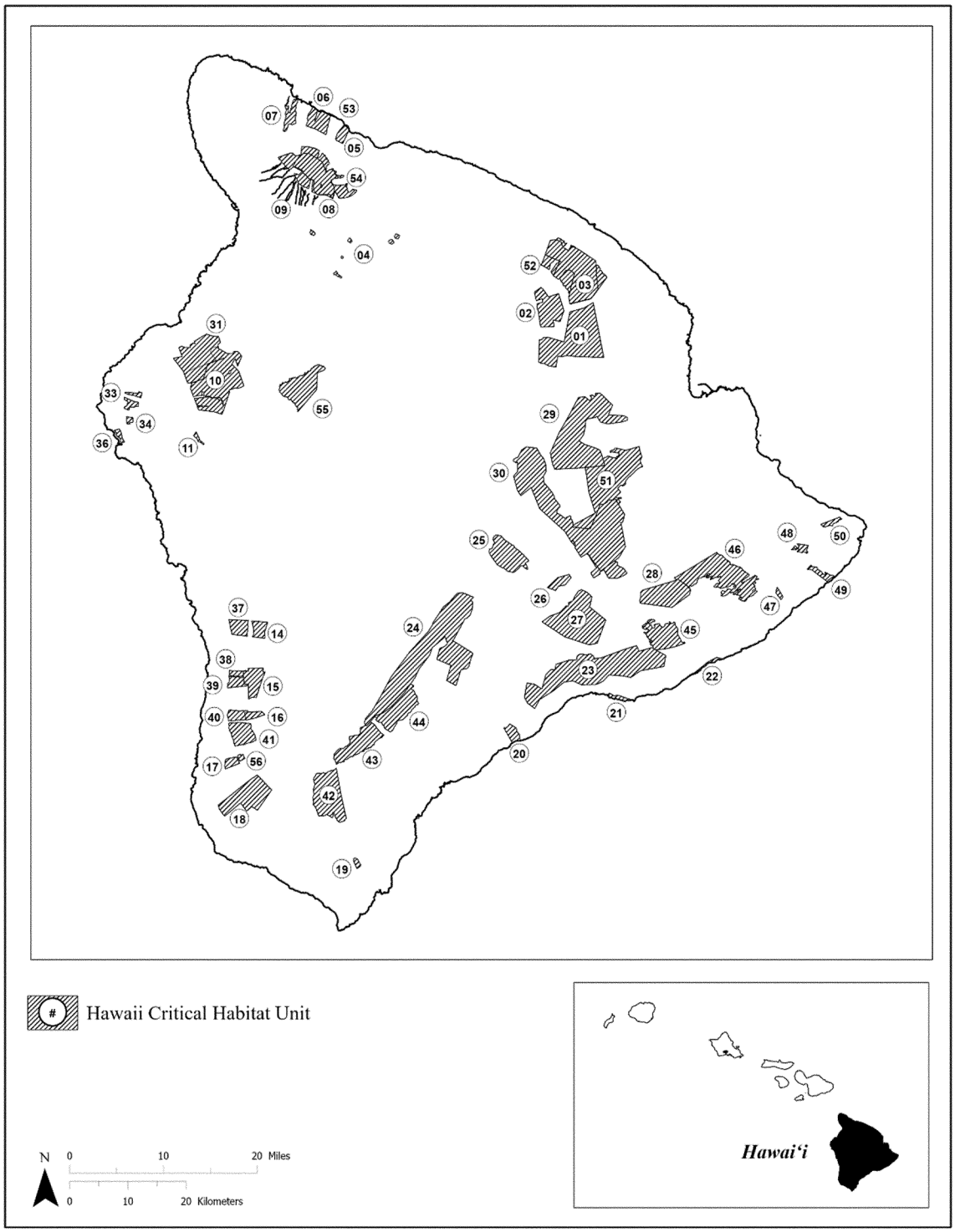
(k) *Maps and critical habitat unit descriptions for the island of Hawaii, HI.* Critical habitat units are described in this paragraph (k). Map coordinates were created using World Geodetic System 1984 (WGS84). The map in paragraph (k)(1) shows the general locations of the critical habitat units designated on the island of Hawaii. Existing humanmade features and structures, such as buildings, aqueducts, runways, roads, and other paved areas, and the land on which they are located existing within the legal boundaries on April 11, 2024 are not included in the critical habitat designation. Federal actions limited to those areas, therefore, would not trigger a consultation under section 7 of the Act unless they may affect the species or physical or biological features in adjacent critical habitat.

(1) Index map follows:

Figure 1 to paragraph (k)

Map 1

Hawaii Critical Habitat—Island Index Map



* * * * *

(12) Hawaii 3—*Cyanea tritomantha*-a (12,059 ac; 4,880 ha).

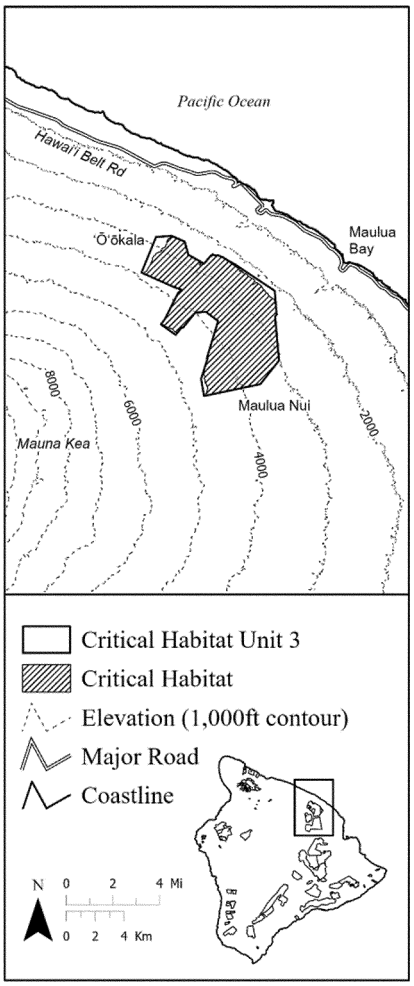
(i) This unit is also critical habitat for Hawaii 3—*Cyrtandra wagneri*-a, Hawaii 3—*Melicope remyi*-a, Hawaii 3—*Phyllostegia floribunda*-a, Hawaii 3—*Pittosporum hawaiiense*-a, Hawaii 3—*Schiedea diffusa* ssp. *macraei*-a, and Hawaii 3—*Stenogyne cranwelliae*-a (see paragraphs (k)(15), (k)(16), (k)(17), (k)(19), (k)(20), (k)(21), respectively, of this section).

(ii) Map 11a follows:

Figure 12 to paragraph (k)

Map 11a

Hawaii 3—*Cyanea tritomantha*-a, Hawaii 3—*Cyrtandra wagneri*-a, Hawaii 3—*Melicope remyi*-a, Hawaii 3—*Phyllostegia floribunda*-a, Hawaii 3—*Pittosporum hawaiiense*-a, Hawaii 3—*Schiedea diffusa* ssp. *macraei*-a, Hawaii 3—*Stenogyne cranwelliae*-a



* * * * *

(15) Hawaii 3—*Cyrtandra wagneri*-a (12,059 ac; 4,880 ha). See paragraph (k)(12)(ii) of this section for the map of this unit.

(16) Hawaii 3—*Melicope remyi*-a (12,059 ac; 4,880 ha). See paragraph (k)(12)(ii) of this section for the map of this unit.

(17) Hawaii 3—*Phyllostegia floribunda*-a (12,059 ac; 4,880 ha). See paragraph (k)(12)(ii) of this section for the map of this unit.

* * * * *

(19) Hawaii 3—*Pittosporum hawaiiense*-a (12,059 ac; 4,880 ha). See paragraph (k)(12)(ii) of this section for the map of this unit.

(20) Hawaii 3—*Schiedea diffusa* ssp. *macraei*-a (12,059 ac; 4,880 ha). See paragraph (k)(12)(ii) of this section for the map of this unit.

(21) Hawaii 3—*Stenogyne cranwelliae*-a (12,059 ac; 4,880 ha). See paragraph (k)(12)(ii) of this section for the map of this unit.

* * * * *

(32) Hawaii 6—*Bidens hillebrandiana* ssp. *hillebrandiana*-a (2 ac; 1 ha).

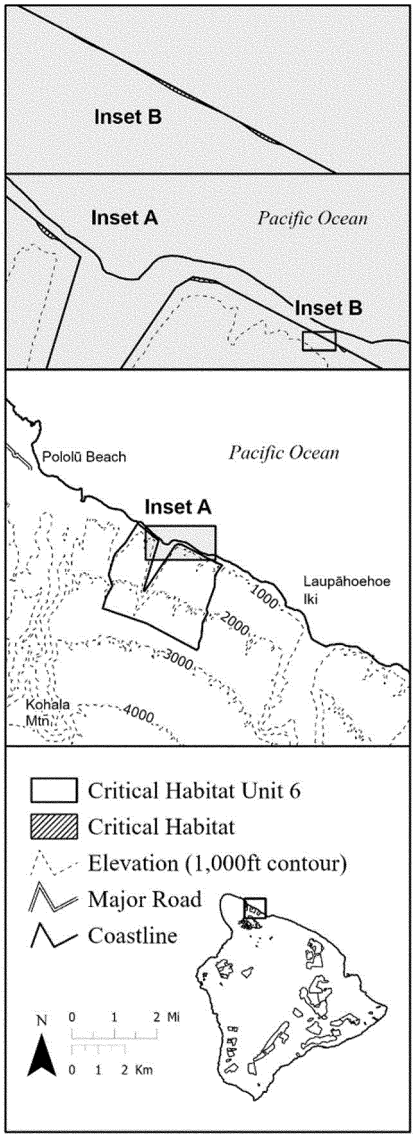
(i) [Reserved].

(ii) Map 24a follows:

Figure 26 to paragraph (k)

Map 24a

Hawaii 6—*Bidens hillebrandiana* ssp. *hillebrandiana*-a



* * * * *

(36) Hawaii 8—*Cyanea tritomantha*-b (6,805 ac; 2,754 ha).

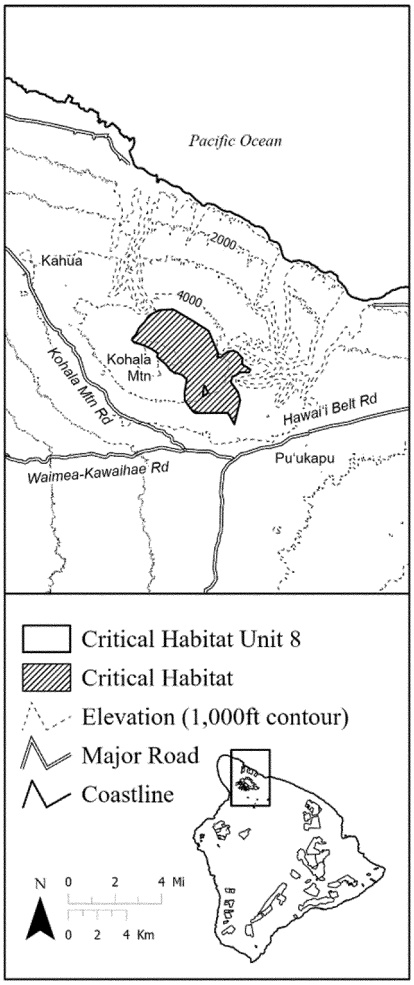
(i) This unit is also critical habitat for Hawaii 8—*Melicope remyi*-b, Hawaii 8—*Phyllostegia floribunda*-b, Hawaii 8—*Pittosporum hawaiiense*-b, Hawaii 8—*Schiedea diffusa* ssp. *macraei*-b, and Hawaii 8—*Stenogyne cranwelliae*-b (see paragraphs (k)(37), (k)(38), (k)(40), (k)(41), and (k)(42), respectively, of this section).

(ii) Map 27a follows:

Figure 30 to paragraph (k)

Map 27a

Hawaii 8—*Cyanea tritomantha*-b, Hawaii 8—*Melicope remyi*-b, Hawaii 8—*Phyllostegia floribunda*-b, Hawaii 8—*Pittosporum hawaiiense*-b, Hawaii 8—*Schiedea diffusa* ssp. *macraei*-b, Hawaii 8—*Stenogyne cranwelliae*-b



(37) Hawaii 8—*Melicope remyi*-b (6,805 ac; 2,754 ha). See paragraph (k)(36)(ii) of this section for the map of this unit.

(38) Hawaii 8—*Phyllostegia floribunda*-b (6,805 ac; 2,754 ha). See paragraph (k)(36)(ii) of this section for the map of this unit.

* * * * *

(40) Hawaii 8—*Pittosporum hawaiiense*-b (6,805 ac; 2,754 ha). See paragraph (k)(36)(ii) of this section for the map of this unit.

(41) Hawaii 8—*Schiedea diffusa* ssp. *macraei*-b (6,805 ac; 2,754 ha). See paragraph (k)(36)(ii) of this section for the map of this unit.

(42) Hawaii 8—*Stenogyne cranwelliae*-b (6,805 ac; 2,754 ha). See paragraph (k)(36)(ii) of this section for the map of this unit.

* * * * *

(53) Hawaii 9—*Cyanea tritomantha*-c (1 ac; <1 ha).

(i) This unit is also critical habitat for Hawaii 9—*Melicope remyi*-c, Hawaii 9—*Phyllostegia floribunda*-c, Hawaii 9—*Pittosporum hawaiiense*-c, Hawaii 9—*Schiedea diffusa* ssp. *macraei*-c, and

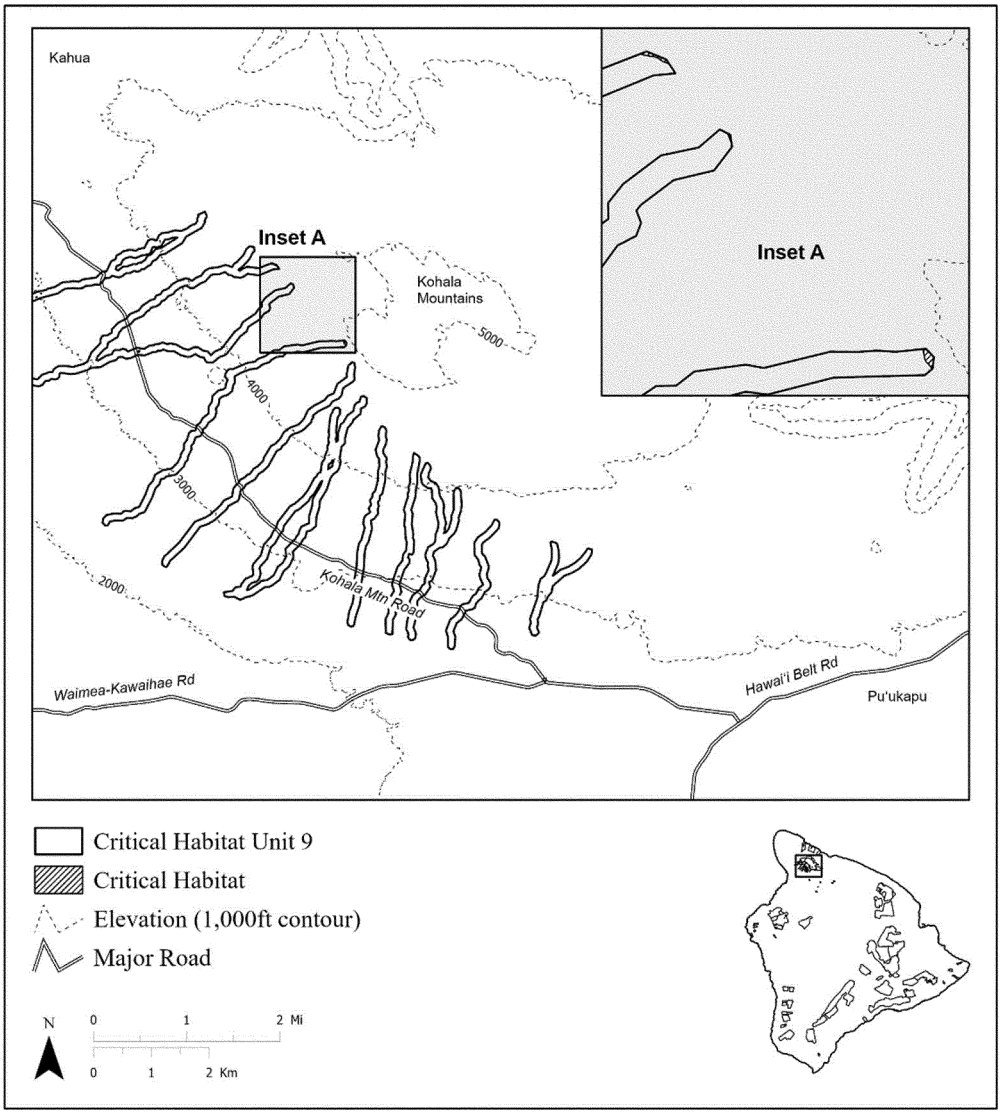
Hawaii 9—*Stenogyne cranwelliae*-c (see paragraphs (k)(54), (k)(55), (k)(56), (k)(57), and (k)(58) respectively, of this section).

(ii) Map 38a follows:

Figure 42 to paragraph (k)

Map 38a

Hawaii 9—*Cyanea tritomantha*-c, Hawaii 9—*Melicope remyi*-c, Hawaii 9—*Phyllostegia floribunda*-c, Hawaii 9—*Pittosporum hawaiiense*-c, Hawaii 9—*Schiedea diffusa* ssp. *macraei*-c, Hawaii 9—*Stenogyne cranwelliae*-c



(54) Hawaii 9—*Melicope remyi*-c (1 ac; <1 ha). See paragraph (k)(53)(ii) of this section for the map of this unit.

(55) Hawaii 9—*Phyllostegia floribunda*-c (1 ac; <1 ha). See paragraph (k)(53)(ii) of this section for the map of this unit.

(56) Hawaii 9–*Pittosporum hawaiiense*-c (1 ac; < 1 ha). See paragraph (k)(53)(ii) of this section for the map of this unit.

(57) Hawaii 9–*Schiedea diffusa* ssp. *macraei*-c (1 ac; < 1 ha). See paragraph (k)(53)(ii) of this section for the map of this unit.

(58) Hawaii 9–*Stenogyne cranwelliae*-c (1 ac; < 1 ha). See paragraph (k)(53)(ii) of this section for the map of this unit.

* * * * *

(79) Hawaii 15–*Cyanea marksii*-a-Section 4 (182 ac; 73 ha).

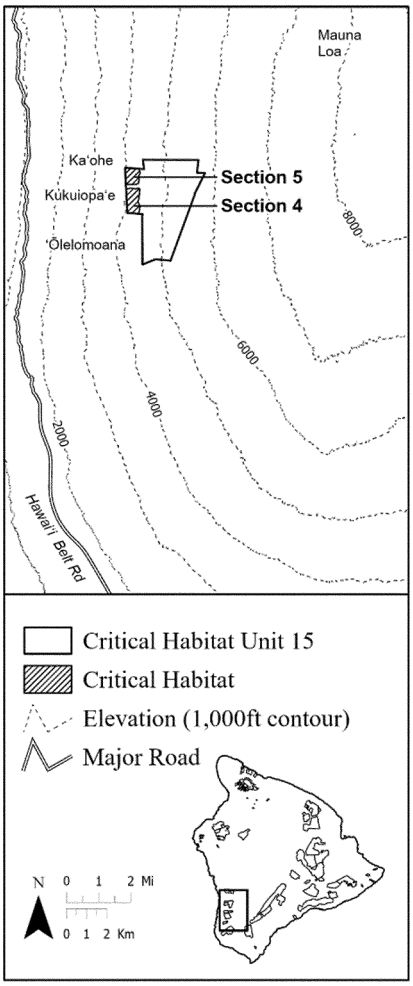
(i) This unit is also critical habitat for Hawaii 15–*Phyllostegia floribunda*-d-Section 4, Hawaii 15–*Pittosporum hawaiiense*-d-Section 4, Hawaii 15–*Schiedea diffusa* ssp. *macraei*-d-Section 4, and Hawaii 15–*Stenogyne cranwelliae*-d-Section 4 (see paragraphs (k)(82), (k)(84), (k)(86), and (k)(88), respectively, of this section).

(ii) Map 58a follows:

Figure 60 to paragraph (k)

Map 58a

Hawaii 15–*Cyanea marksii*-a-Section 4, Hawaii 15–*Cyanea marksii*-b-Section 5, Hawaii 15–*Phyllostegia floribunda*-d-Section 4, Hawaii 15–*Phyllostegia floribunda*-e-Section 5, Hawaii 15–*Pittosporum hawaiiense*-d-Section 4, Hawaii 15–*Pittosporum hawaiiense*-e-Section 5, Hawaii 15–*Schiedea diffusa* ssp. *macraei*-d-Section 4, Hawaii 15–*Schiedea diffusa* ssp. *macraei*-e-Section 5, Hawaii 15–*Stenogyne cranwelliae*-d-Section 4, Hawaii 15–*Stenogyne cranwelliae*-e-Section 5



(80) Hawaii 15–*Cyanea marksii*-b-Section 5 (127 ac; 51 ha).

(i) This unit is also critical habitat for Hawaii 15–*Phyllostegia floribunda*-e-Section 5, Hawaii 15–*Pittosporum hawaiiense*-e-Section 5, Hawaii 15–*Schiedea diffusa* ssp. *macraei*-e-Section 5, and Hawaii 15–*Stenogyne cranwelliae*-e-Section 5 (see paragraphs (k)(83), (k)(85), (k)(87), and (k)(89), respectively, of this section).

(ii) See paragraph (k)(79)(ii) of this section for the map of this unit.

* * * * *

(82) Hawaii 15–*Phyllostegia floribunda*-d-Section 4 (182 ac; 73 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(83) Hawaii 15–*Phyllostegia floribunda*-e-Section 5 (127 ac; 51 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(84) Hawaii 15–*Pittosporum hawaiiense*-d-Section 4 (182 ac; 73 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(85) Hawaii 15–*Pittosporum hawaiiense*-e-Section 5 (127 ac; 51 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(86) Hawaii 15–*Schiedea diffusa* ssp. *macraei*-d-Section 4 (182 ac; 73 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(87) Hawaii 15–*Schiedea diffusa* ssp. *macraei*-e-Section 5 (127 ac; 51 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(88) Hawaii 15–*Stenogyne cranwelliae*-d-Section 4 (182 ac; 73 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

(89) Hawaii 15–*Stenogyne cranwelliae*-e-Section 5 (127 ac; 51 ha). See paragraph (k)(79)(ii) of this section for the map of this unit.

* * * * *

(91) Hawaii 16–*Cyanea marksii*-c (156 ac; 63 ha).

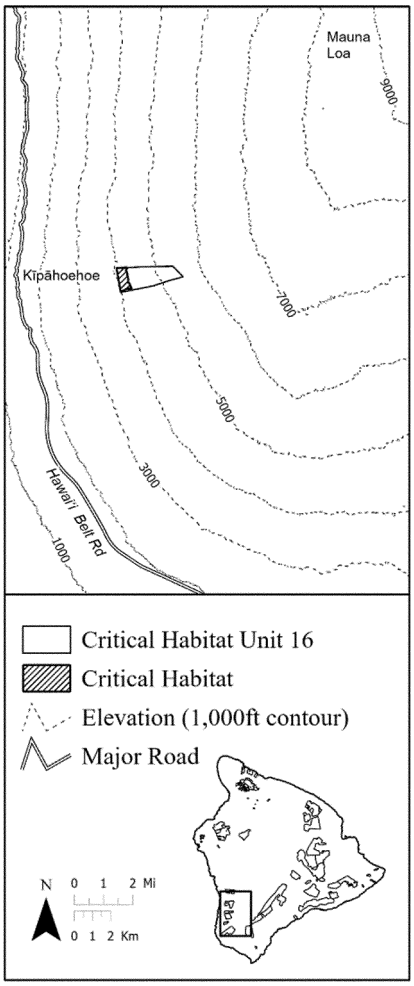
(i) This unit is also critical habitat for Hawaii 16–*Phyllostegia floribunda*-f, Hawaii 16–*Pittosporum hawaiiense*-f, Hawaii 16–*Schiedea diffusa* ssp. *macraei*-f, and Hawaii 16–*Stenogyne cranwelliae*-f (see paragraphs (k)(93), (k)(94), (k)(95), and (k)(96), respectively, of this section).

(ii) Map 60a follows:

Figure 63 to paragraph (k)

Map 60a

Hawaii 16–*Cyanea marksii*-c, Hawaii 16–*Phyllostegia floribunda*-f, Hawaii 16–*Pittosporum hawaiiense*-f, Hawaii 16–*Schiedea diffusa* ssp. *macraei*-f, Hawaii 16–*Stenogyne cranwelliae*-f



* * * * *

(93) Hawaii 16–*Phyllostegia floribunda*-f (156 ac; 63 ha). See paragraph (k)(91)(ii) of this section for the map of this unit.

(94) Hawaii 16–*Pittosporum hawaiiense*-f (156 ac; 63 ha). See paragraph (k)(91)(ii) of this section for the map of this unit.

(95) Hawaii 16–*Schiedea diffusa* ssp. *macraei*-f (156 ac; 63 ha). See paragraph (k)(91)(ii) of this section for the map of this unit.

(96) Hawaii 16–*Stenogyne cranwelliae*-f (156 ac; 63 ha). See paragraph (k)(91)(ii) of this section for the map of this unit.

* * * * *

(110) Hawaii 23–*Phyllostegia floribunda*-g (9 ac; 4 ha).

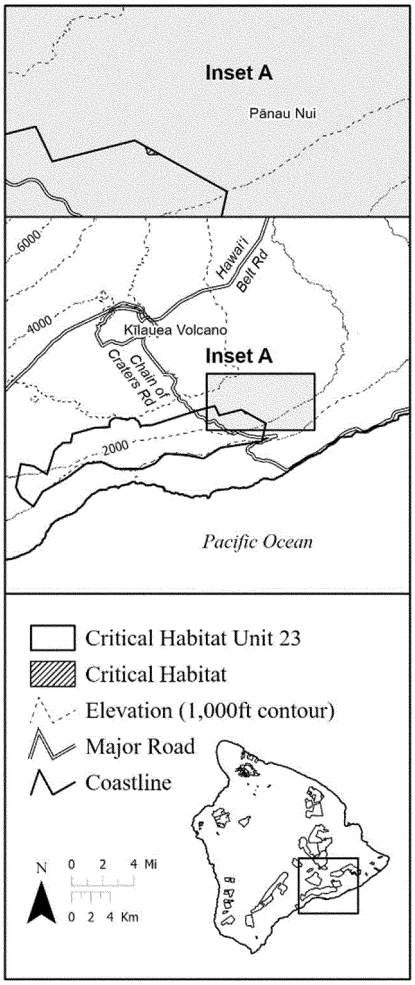
(i) This unit is also critical habitat for Hawaii 23–*Pittosporum hawaiiense*-g (see paragraph (k)(111) of this section).

(ii) Map 74a follows:

Figure 78 to paragraph (k)

Map 74a

Hawaii 23–*Phyllostegia floribunda*-g, Hawaii 23–*Pittosporum hawaiiense*-g



(111) Hawaii 23–*Pittosporum hawaiiense*-g (9 ac; 4 ha). See paragraph (k)(110)(ii) of this section for the map of this unit.

* * * * *

(116) Hawaii 24–*Cyanea tritomantha*-d-Section 8 (1,956 ac; 792 ha).

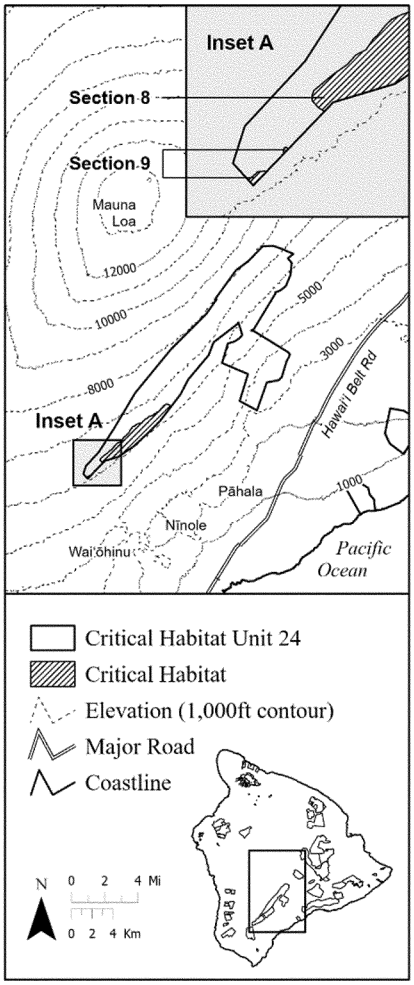
(i) This unit is also critical habitat for Hawaii 24–*Pittosporum hawaiiense*-h-Section 8, Hawaii 24–*Schiedea diffusa* ssp. *macraei*-g-Section 8, and Hawaii 24–*Stenogyne cranwelliae*-g-Section 8 (see paragraphs (k)(119), (k)(122), and (k)(124), respectively, of this section).

(ii) Map 78a follows:

Figure 83 to paragraph (k)

Map 78a

Hawaii 24–*Cyanea tritomantha*-d-Section 8, Hawaii 24–*Pittosporum hawaiiense*-h-Section 8, Hawaii 24–*Pittosporum hawaiiense*-i-Section 9, Hawaii 24–*Schiedea diffusa* ssp. *macraei*-g-Section 8, Hawaii 24–*Schiedea diffusa* ssp. *macraei*-h-Section 9, Hawaii 24–*Stenogyne cranwelliae*-g-Section 8, Hawaii 24–*Stenogyne cranwelliae*-h-Section 9



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(119) Hawaii 24–*Pittosporum hawaiiense*-h-Section 8 (1,956 ac; 792 ha). See paragraph (k)(116)(ii) of this section for the map of this unit.

(120) Hawaii 24–*Pittosporum hawaiiense*-i-Section 9 (101 ac; 41 ha).

(i) This unit is also critical habitat for Hawaii 24–*Schiedea diffusa* ssp. *macraei*-h-Section 9 and Hawaii 24–*Stenogyne cranwelliae*-h-Section 9 (see paragraphs (k)(123) and (k)(125), respectively, of this section).

(ii) See paragraph (k)(116)(ii) of this section for the map of this unit.

* * * * *

(122) Hawaii 24–*Schiedea diffusa* ssp. *macraei*-g-Section 8 (1,956 ac; 792 ha). See paragraph (k)(116)(ii) of this section for the map of this unit.

(123) Hawaii 24–*Schiedea diffusa* ssp. *macraei*-h-Section 9 (101 ac; 41 ha). See paragraph (k)(116)(ii) of this section for the map of this unit.

(124) Hawaii 24–*Stenogyne cranwelliae*-g-Section 8 (1,956 ac; 792 ha). See paragraph (k)(116)(ii) of this section for the map of this unit.

(125) Hawaii 24–*Stenogyne cranwelliae*-h-Section 9 (101 ac; 41 ha). See paragraph (k)(116)(ii) of this section for the map of this unit.

* * * * *

(134) Hawaii 28–*Cyrtandra nanawaleensis*-a (155 ac; 63 ha).

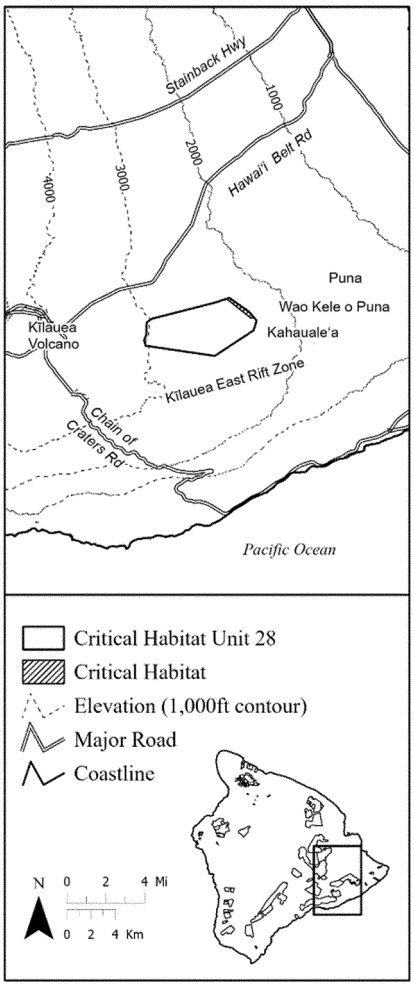
(i) This unit is also critical habitat for Hawaii 28–*Phyllostegia floribunda*-h (see paragraph (k)(135) of this section).

(ii) Map 89a follows:

Figure 95 to paragraph (k)

Map 89a

Hawaii 28–*Cyrtandra nanawaleensis*-a, Hawaii 28–*Phyllostegia floribunda*-h



(135) Hawaii 28–*Phyllostegia floribunda*-h (155 ac; 63 ha). See paragraph (k)(134)(ii) of this section for the map of this unit.

* * * * *

(138) Hawaii 29–*Cyanea tritomantha*-e (494 ac; 200 ha).

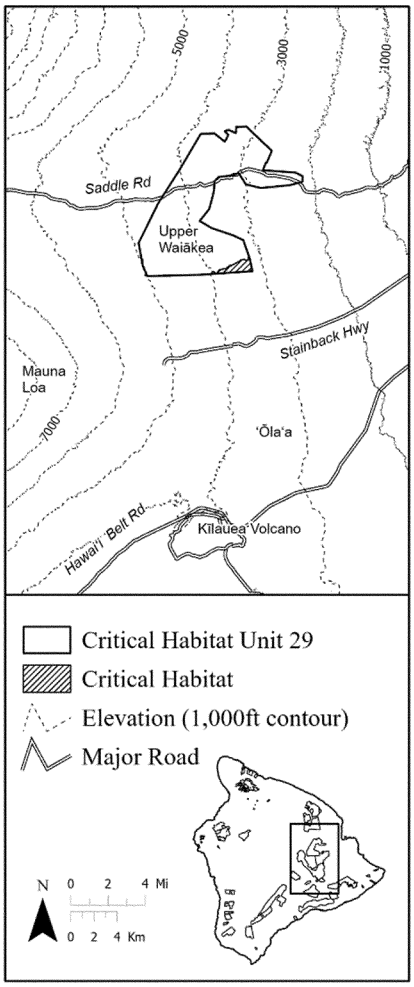
(i) This unit is also critical habitat for Hawaii 29–*Phyllostegia floribunda*-i, Hawaii 29–*Pittosporum hawaiiense*-j, Hawaii 29–*Schiedea diffusa* ssp. *macraei*-i, and Hawaii 29–*Stenogyne cranwelliae*-i (see paragraphs (k)(141), (k)(142), (k)(143), and (k)(144), respectively, of this section).

(ii) Map 91a follows:

Figure 98 to paragraph (k)

Map 91a

Hawaii 29–*Cyanea tritomantha*-e, Hawaii 29–*Phyllostegia floribunda*-i, Hawaii 29–*Pittosporum hawaiiense*-j, Hawaii 29–*Schiedea diffusa* ssp. *macraei*-i, Hawaii 29–*Stenogyne cranwelliae*-I



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(141) Hawaii 29–*Phyllostegia floribunda*-i (494 ac; 200 ha). See paragraph (k)(138)(ii) of this section for the map of this unit.

(142) Hawaii 29–*Pittosporum hawaiiense*-j (494 ac; 200 ha). See paragraph (k)(138)(ii) of this section for the map of this unit.

(143) Hawaii 29–*Schiedea diffusa* ssp. *macraei*-i (494 ac; 200 ha). See paragraph (k)(138)(ii) of this section for the map of this unit.

(144) Hawaii 29–*Stenogyne cranwelliae*-i (494 ac; 200 ha). See paragraph (k)(138)(ii) of this section for the map of this unit.

* * * * *

(150) Hawaii 30–*Cyanea tritomantha*-f (13,730 ac; 5,556 ha).

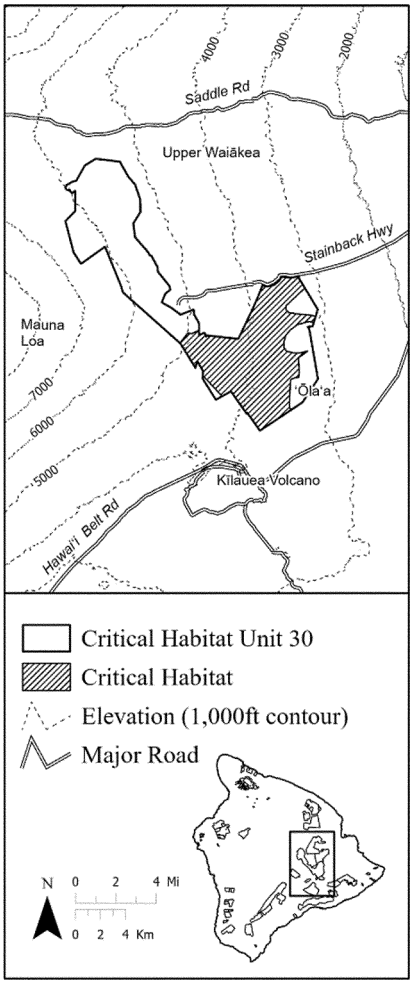
(i) This unit is also critical habitat for Hawaii 30–*Phyllostegia floribunda*-j, Hawaii 30–*Pittosporum hawaiiense*-k, Hawaii 30–*Schiedea diffusa* ssp. *macraei*-j, and Hawaii 30–*Stenogyne cranwelliae*-j (see paragraphs (k)(152), (k)(155), (k)(157), and (k)(159), respectively, of this section).

(ii) Map 98a follows:

Figure 106 to paragraph (k)

Map 98a

Hawaii 30–*Cyanea tritomantha*-f, Hawaii 30–*Phyllostegia floribunda*-j, Hawaii 30–*Pittosporum hawaiiense*-k, Hawaii 30–*Schiedea diffusa* ssp. *macraei*-j, Hawaii 30–*Stenogyne cranwelliae*-j



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(152) Hawaii 30–*Phyllostegia floribunda*-j (13,730 ac; 5,556 ha). See paragraph (k)(150)(ii) of this section for the map of this unit.

* * * * *

(155) Hawaii 30–*Pittosporum hawaiiense*-k (13,730 ac; 5,556 ha). See paragraph (k)(150)(ii) of this section for the map of this unit.

* * * * *

(157) Hawaii 30–*Schiedea diffusa* ssp. *macraei*-j (13,730 ac; 5,556 ha). See paragraph (k)(150)(ii) of this section for the map of this unit.

* * * * *

(159) Hawaii 30–*Stenogyne cranwelliae*-j (13,730 ac; 5,556 ha). See paragraph (k)(150)(ii) of this section for the map of this unit.

* * * * *

(171) Hawaii 37–*Cyanea marksii*-d (1,906 ac; 771 ha)

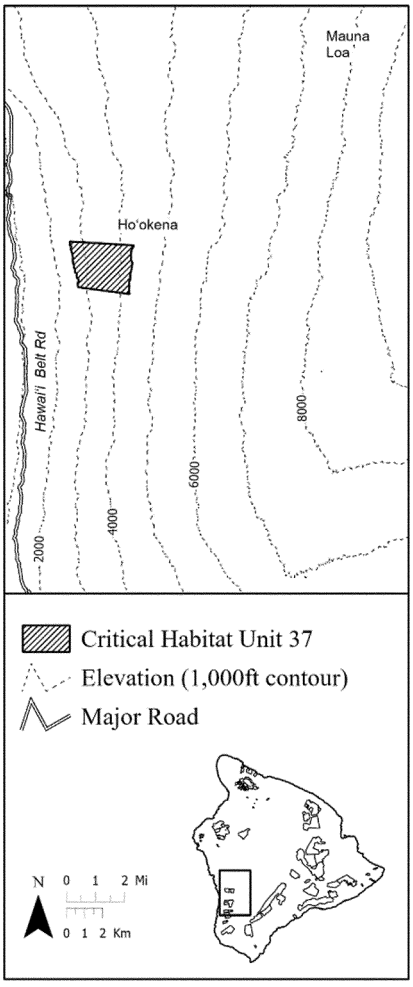
(i) This unit is also critical habitat for Hawaii 37–*Phyllostegia floribunda*-k, Hawaii 37–*Pittosporum hawaiiense*-l, Hawaii 37–*Schiedea diffusa* ssp. *macraei*-k, and Hawaii 37–*Stenogyne cranwelliae*-k (see paragraphs (k)(172), (k)(173), (k)(174), and (k)(175), respectively, of this section).

(ii) Map 106 follows:

Figure 114 to paragraph (k)

Map 106

Hawaii 37–*Cyanea marksii*-d, Hawaii 37–*Phyllostegia floribunda*-k, Hawaii 37–*Pittosporum hawaiiense*-l, Hawaii 37–*Schiedea diffusa* ssp. *macraei*-k, Hawaii 37–*Stenogyne cranwelliae*-k



(172) Hawaii 37–*Phyllostegia floribunda*-k (1,906 ac; 771 ha). See paragraph (k)(171)(ii) of this section for the map of this unit.

(173) Hawaii 37–*Pittosporum hawaiiense*-l (1,906 ac; 771 ha). See paragraph (k)(171)(ii) of this section for the map of this unit.

(174) Hawaii 37–*Schiedea diffusa* ssp. *macraei*-k (1,906 ac; 771 ha). See paragraph (k)(171)(ii) of this section for the map of this unit.

(175) Hawaii 37–*Stenogyne cranwelliae*-k (1,906 ac; 771 ha). See paragraph (k)(171)(ii) of this section for the map of this unit.

(176) Hawaii 38–*Cyanea marksii*-e (534 ac; 216 ha).

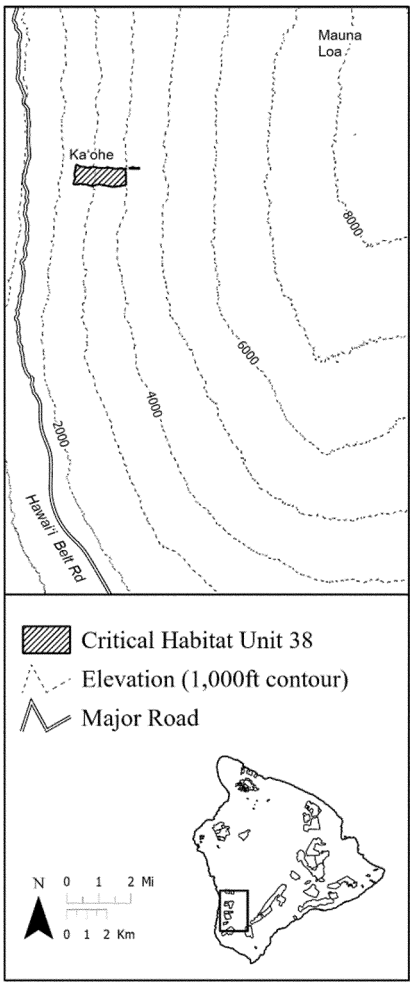
(i) This unit is also critical habitat for Hawaii 38–*Phyllostegia floribunda*-l, Hawaii 38–*Pittosporum hawaiiense*-m, Hawaii 38–*Schiedea diffusa* ssp. *macraei*-l, and Hawaii 38–*Stenogyne cranwelliae*-l (see paragraphs (k)(177), (k)(178), (k)(179), and (k)(180), respectively, of this section).

(ii) Map 107 follows:

Figure 115 to paragraph (k)

Map 107

Hawaii 38–*Cyanea marksii*-e, Hawaii 38–*Phyllostegia floribunda*-l, Hawaii 38–*Pittosporum hawaiiense*-m, Hawaii 38–*Schiedea diffusa* ssp. *macraei*-l, Hawaii 38–*Stenogyne cranwelliae*-l



(177) Hawaii 38–*Phyllostegia floribunda*-l (534 ac; 216 ha). See paragraph (k)(176)(ii) of this section for the map of this unit.

(178) Hawaii 38–*Pittosporum hawaiiense*-m (534 ac; 216 ha). See paragraph (k)(176)(ii) of this section for the map of this unit.

(179) Hawaii 38–*Schiedea diffusa* ssp. *macraei*-l (534 ac; 216 ha). See paragraph (k)(176)(ii) of this section for the map of this unit.

(180) Hawaii 38–*Stenogyne cranwelliae*-l (534 ac; 216 ha). See paragraph (k)(176)(ii) of this section for the map of this unit.

(181) Hawaii 39–*Cyanea marksii*-f (1,164 ac; 471 ha)

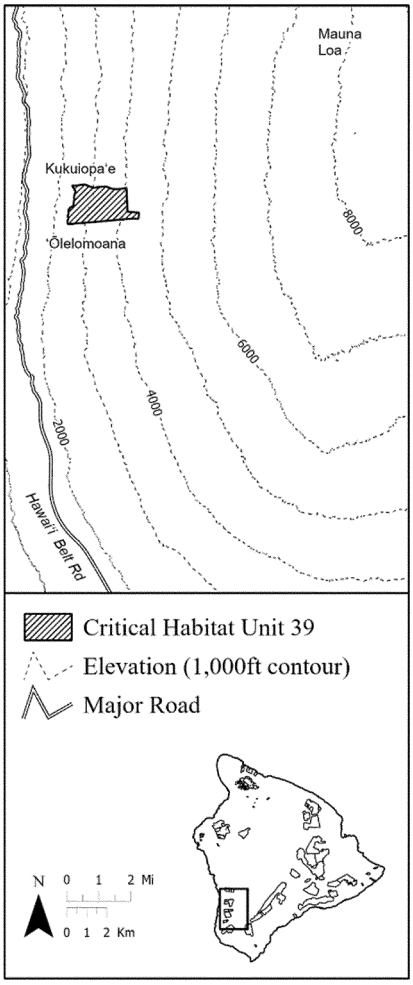
(i) This unit is also critical habitat for Hawaii 39–*Phyllostegia floribunda*-m, Hawaii 39–*Pittosporum hawaiiense*-n, Hawaii 39–*Schiedea diffusa* ssp. *macraei*-m, and Hawaii 39–*Stenogyne cranwelliae*-m (see paragraphs (k)(182), (k)(183), (k)(184), and (k)(185), respectively, of this section).

(ii) Map 108 follows:

Figure 116 to paragraph (k)

Map 108

Hawaii 39–*Cyanea marksii*-f, Hawaii 39–*Phyllostegia floribunda*-m, Hawaii 39–*Pittosporum hawaiiense*-n, Hawaii 39–*Schiedea diffusa* ssp. *macraei*-m, Hawaii 39–*Stenogyne cranwelliae*-m



(182) Hawaii 39–*Phyllostegia floribunda*-m (1,164 ac; 471 ha). See paragraph (k)(181)(ii) of this section for the map of this unit.

(183) Hawaii 39–*Pittosporum hawaiiense*-n (1,164 ac; 471 ha). See paragraph (k)(181)(ii) of this section for the map of this unit.

(184) Hawaii 39–*Schiedea diffusa* ssp. *macraei*-m (1,164 ac; 471 ha). See paragraph (k)(181)(ii) of this section for the map of this unit.

(185) Hawaii 39–*Stenogyne cranwelliae*-m (1,164 ac; 471 ha). See paragraph (k)(181)(ii) of this section for the map of this unit.

(186) Hawaii 40–*Cyanea marksii*-g (1,243 ac; 503 ha)

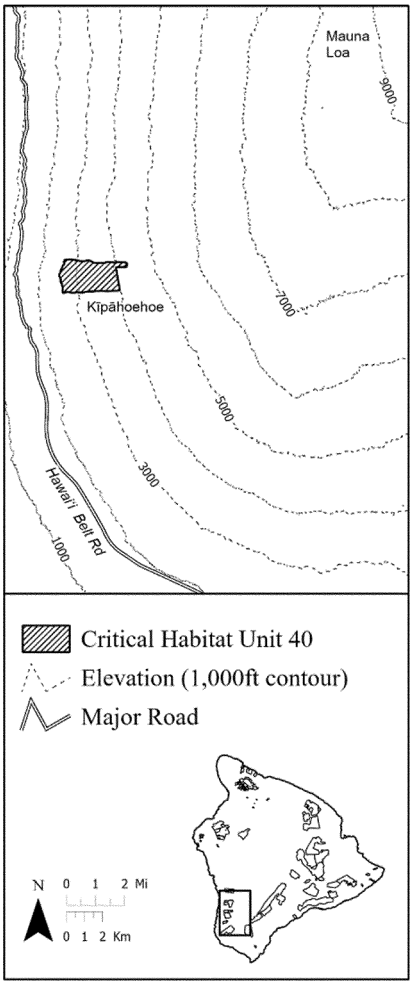
(i) This unit is also critical habitat for Hawaii 40–*Phyllostegia floribunda*-n, Hawaii 40–*Pittosporum hawaiiense*-o, Hawaii 40–*Schiedea diffusa* ssp. *macraei*-n, and Hawaii 40–*Stenogyne cranwelliae*-n (see paragraphs (k)(187), (k)(188), (k)(189), and (k)(190), respectively, of this section).

(ii) Map 109 follows:

Figure 117 to paragraph (k)

Map 109

Hawaii 40–*Cyanea marksii*-g, Hawaii 40–*Phyllostegia floribunda*-n, Hawaii 40–*Pittosporum hawaiiense*-o, Hawaii 40–*Schiedea diffusa ssp. macraei*-n, Hawaii 40–*Stenogyne cranwelliae*-n



(187) Hawaii 40–*Phyllostegia floribunda*-n (1,243 ac; 503 ha). See paragraph (k)(186)(ii) of this section for the map of this unit.

(188) Hawaii 40–*Pittosporum hawaiiense*-o (1,243 ac; 503 ha). See paragraph (k)(186)(ii) of this section for the map of this unit.

(189) Hawaii 40–*Schiedea diffusa* ssp. *macraei*-n (1,243 ac; 503 ha). See paragraph (k)(186)(ii) of this section for the map of this unit.

(190) Hawaii 40–*Stenogyne cranwelliae*-n (1,243 ac; 503 ha). See paragraph (k)(186)(ii) of this section for the map of this unit.

(191) Hawaii 41–*Cyanea marksii*-h (3,412 ac; 1,381 ha)

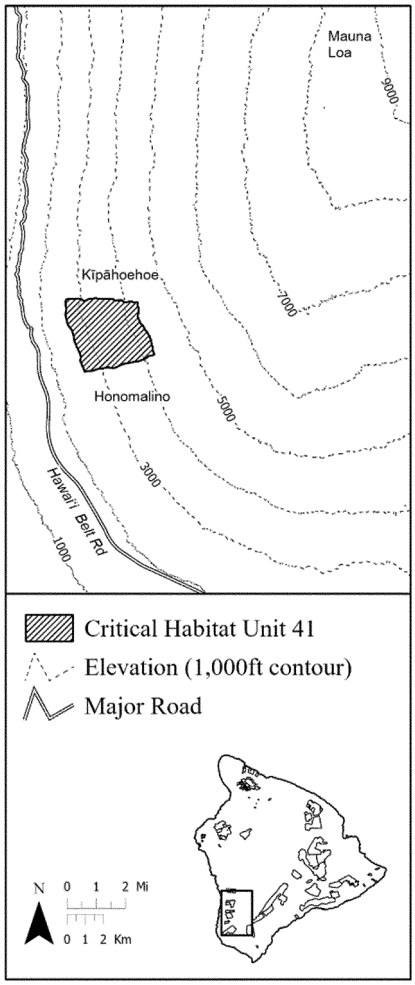
(i) This unit is also critical habitat for Hawaii 41–*Phyllostegia floribunda*-o, Hawaii 41–*Pittosporum hawaiiense*-p, Hawaii 41–*Schiedea diffusa* ssp. *macraei*-o, and Hawaii 41–*Stenogyne cranwelliae*-o (see paragraphs (k)(192), (k)(193), (k)(194), and (k)(195), respectively, of this section).

(ii) Map 110 follows:

Figure 118 to paragraph (k)

Map 110

Hawaii 41–*Cyanea marksii*-h, Hawaii 41–*Phyllostegia floribunda*-o, Hawaii 41–*Pittosporum hawaiiense*-p, Hawaii 41–*Schiedea diffusa* ssp. *macraei*-o, Hawaii 41–*Stenogyne cranwelliae*-o



(192) Hawaii 41–*Phyllostegia floribunda*-o (3,412 ac; 1,381 ha). See paragraph (k)(191)(ii) of this section for the map of this unit.

(193) Hawaii 41–*Pittosporum hawaiiense*-p (3,412 ac; 1,381 ha). See paragraph (k)(191)(ii) of this section for the map of this unit.

(194) Hawaii 41–*Schiedea diffusa* ssp. *macraei*-o (3,412 ac; 1,381 ha). See paragraph (k)(191)(ii) of this section for the map of this unit.

(195) Hawaii 41–*Stenogyne cranwelliae*-o (3,412 ac; 1,381 ha). See paragraph (k)(191)(ii) of this section for the map of this unit.

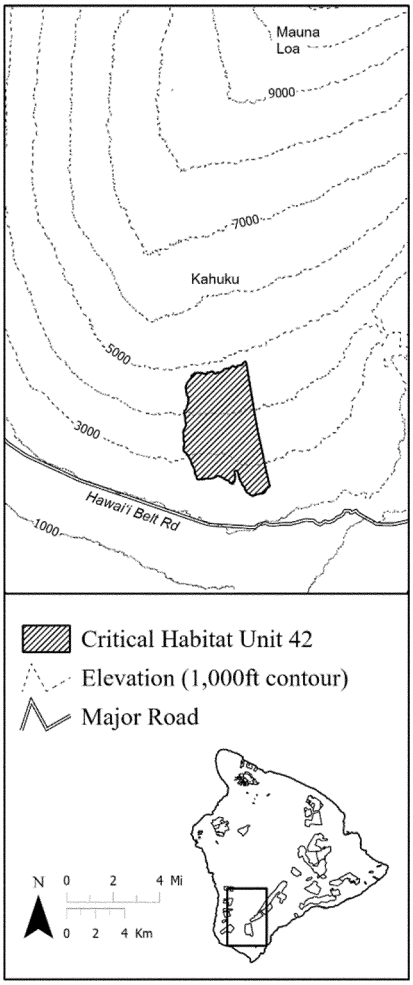
(196) Hawaii 42–*Cyanea tritomantha*-g (8,781 ac; 3,554 ha).

(i) This unit is also critical habitat for Hawaii 42–*Phyllostegia floribunda*-p, Hawaii 42–*Pittosporum hawaiiense*-q, Hawaii 42–*Schiedea diffusa* ssp. *macraei*-p, and Hawaii 42–*Stenogyne cranwelliae*-p (see paragraphs (k)(197), (k)(198), (k)(199), and (k)(200), respectively, of this section).

(ii) Map 111 follows:

Figure 119 to paragraph (k)

Map 111 Hawaii 42–Cyanea tritomantha-g, Hawaii 42–Phyllostegia floribunda-p, Hawaii 42–Pittosporum hawaiiense-q, Hawaii 42–Schiedea diffusa ssp. macraei-p, Hawaii 42–Stenogyne cranwelliae-p



(197) Hawaii 42–*Phyllostegia floribunda*-p (8,781 ac; 3,554 ha). See paragraph (k)(196)(ii) of this section for the map of this unit.

(198) Hawaii 42–*Pittosporum hawaiiense*-q (8,781 ac; 3,554 ha). See paragraph (k)(196)(ii) of this section for the map of this unit.

(199) Hawaii 42–*Schiedea diffusa* ssp. *macraei*-p (8,781 ac; 3,554 ha). See paragraph (k)(196)(ii) of this section for the map of this unit.

(200) Hawaii 42–*Stenogyne cranwelliae*-p (8,781 ac; 3,554 ha). See paragraph (k)(196)(ii) of this section for the map of this unit.

(201) Hawaii 43–*Pittosporum hawaiiense*-r (5,872 ac; 2,376 ha).

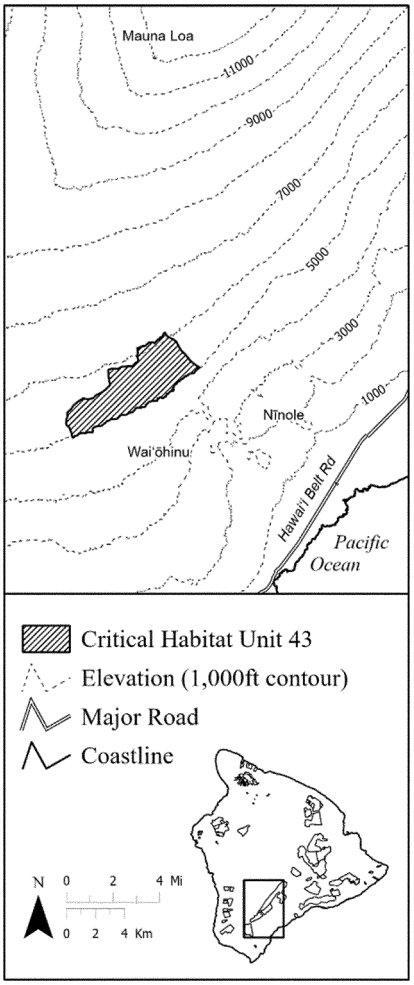
(i) This unit is also critical habitat for Hawaii 43–*Schiedea diffusa* ssp. *macraei*-q and Hawaii 43–*Stenogyne cranwelliae*-q (see paragraphs (k)(202) and (k)(203), respectively, of this section).

(ii) Map 112 follows:

Figure 120 to paragraph (k)

Map 112

Hawaii 43–*Pittosporum hawaiiense*-r, Hawaii 43–*Schiedea diffusa* ssp. *macraei*-q, Hawaii 43–*Stenogyne cranwelliae*-q



(202) Hawaii 43–*Schiedea diffusa* ssp. *macraei*-q (5,872 ac; 2,376 ha). See paragraph (k)(201)(ii) of this section for the map of this unit.

(203) Hawaii 43–*Stenogyne cranwelliae*-q (5,872 ac; 2,376 ha). See paragraph (k)(201)(ii) of this section for the map of this unit.

(204) Hawaii 44–*Cyanea tritomantha*-h (5,884 ac; 2,381 ha).

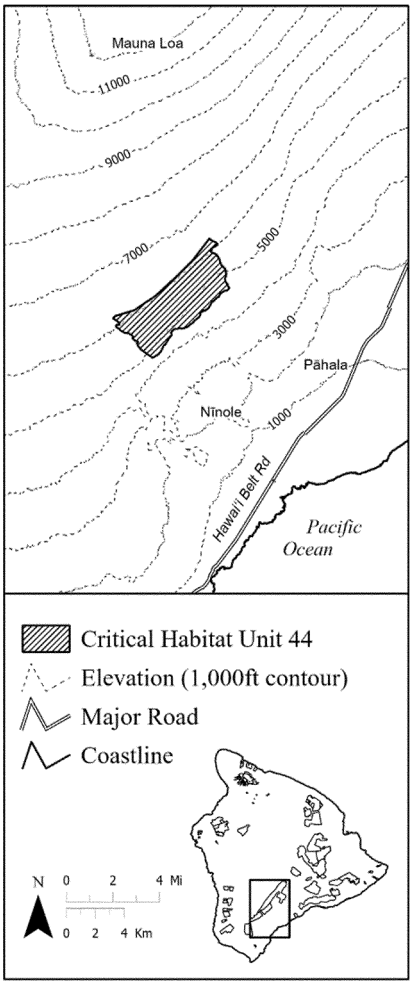
(i) This unit is also critical habitat for Hawaii 44–*Pittosporum hawaiiense*-s, Hawaii 44–*Schiedea diffusa* ssp. *macraei*-r, and Hawaii 44–*Stenogyne cranwelliae*-r (see paragraphs (k)(205), (k)(206), and (k)(207), respectively, of this section).

(ii) Map 113 follows:

Figure 121 to paragraph (k)

Map 113

Hawaii 44–*Cyanea tritomantha*-h, Hawaii 44–*Pittosporum hawaiiense*-s, Hawaii 44–*Schiedea diffusa* ssp. *macraei*-r, Hawaii 44–*Stenogyne cranwelliae*-r



(205) Hawaii 44–*Pittosporum hawaiiense*-s (5,884 ac; 2,381 ha). See paragraph (k)(204)(ii) of this section for the map of this unit.

(206) Hawaii 44–*Schiedea diffusa* ssp. *macraei*-r (5,884 ac; 2,381 ha). See paragraph (k)(204)(ii) of this section for the map of this unit.

(207) Hawaii 44–*Stenogyne cranwelliae*-r (5,884 ac; 2,381 ha). See paragraph (k)(204)(ii) of this section for the map of this unit.

(208) Hawaii 45–*Phyllostegia floribunda*-q (5,494 ac; 2,223 ha).

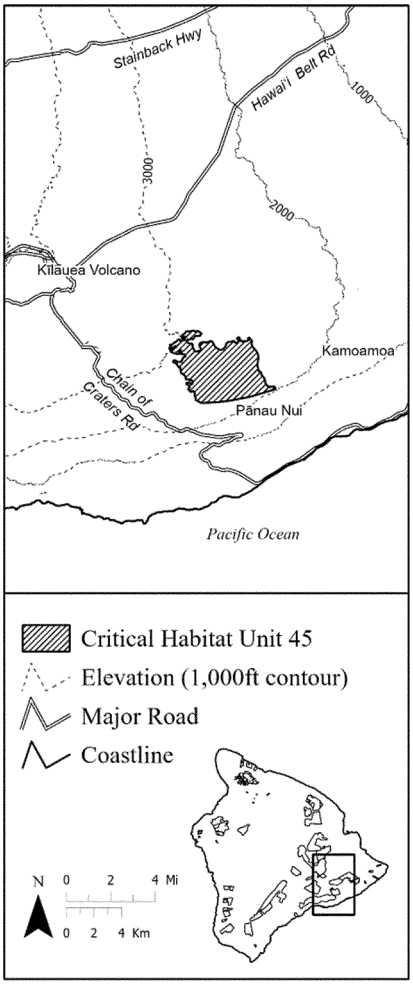
(i) This unit is also critical habitat for Hawaii 45–*Pittosporum hawaiiense*-t (see paragraph (k)(209) of this section).

(ii) Map 114 follows:

Figure 122 to paragraph (k)

Map 114

Hawaii 45–*Phyllostegia floribunda*-q, Hawaii 45–*Pittosporum hawaiiense*-t



(209) Hawaii 45–*Pittosporum hawaiiense*-t (5,494 ac; 2,223 ha). See paragraph (k)(208)(ii) of this section for the map of this unit.

(210) Hawaii 46–*Cyrtandra nanawaleensis*-b (12,219 ac; 4,945 ha)

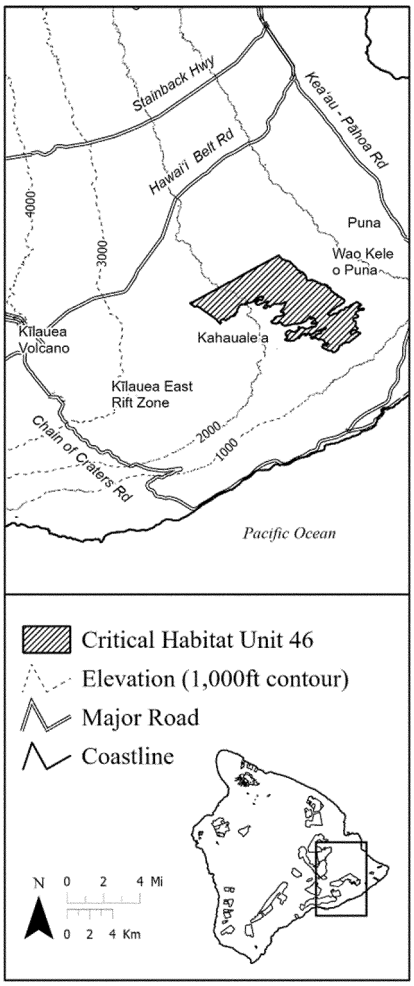
(i) This unit is also critical habitat for Hawaii 46–*Phyllostegia floribunda*-r (see paragraph (k)(211) of this section).

(ii) Map 115 follows:

Figure 123 to paragraph (k)

Map 115

Hawaii 46–*Cyrtandra nanawaleensis*-b, Hawaii 46–*Phyllostegia floribunda*-r



(211) Hawaii 46–*Phyllostegia floribunda*-r (12,219 ac; 4,945 ha). See paragraph (k)(210)(ii) of this section for the map of this unit.

(212) Hawaii 47–*Cyrtandra nanawaleensis*-c (274 ac; 111 ha)

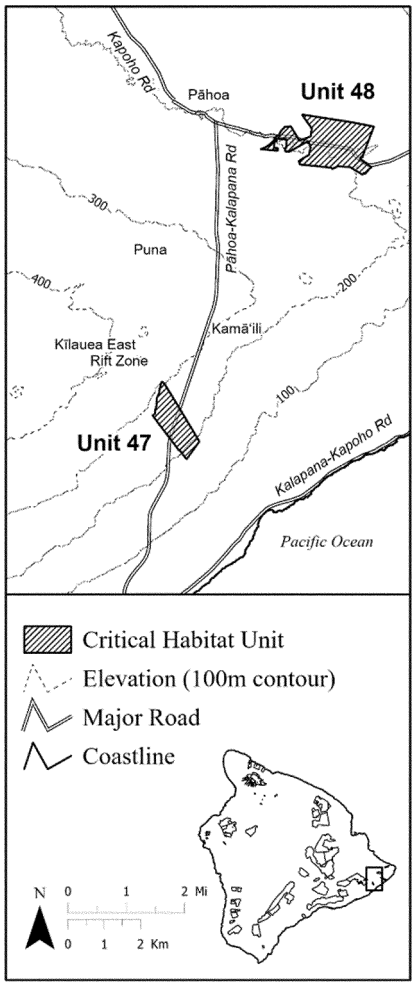
(i) [Reserved].

(ii) Map 116 follows:

Figure 124 to paragraph (k)

Map 116

Hawaii 47–*Cyrtandra nanawaleensis*-c, Hawaii 48–*Cyrtandra nanawaleensis*-d



(213) Hawaii 48–*Cyrtandra nanawaleensis*-d (589 ac; 238 ha). See paragraph (k)(212)(ii) of this section for the map of this unit.

(214) Hawaii 49–*Cyrtandra nanawaleensis*-e (875 ac; 354 ha)

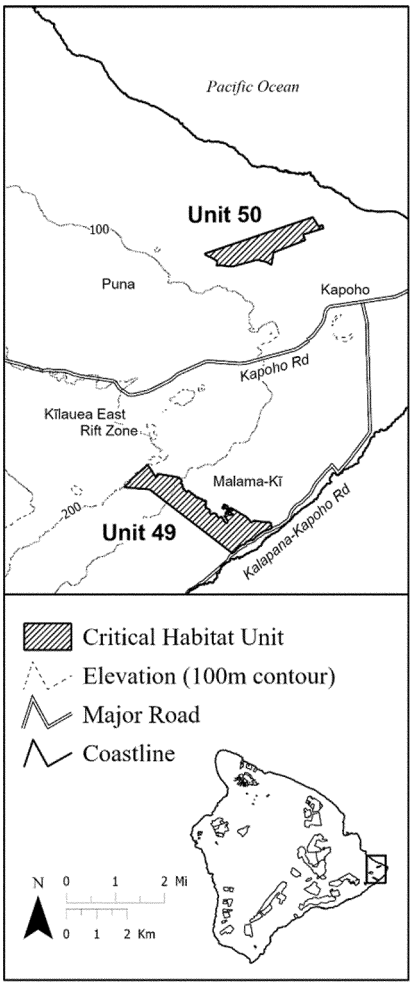
(i) [Reserved].

(ii) Map 117 follows:

Figure 125 to paragraph (k)

Map 117

Hawaii 49–*Cyrtandra nanawaleensis*-e, Hawaii 50–*Cyrtandra nanawaleensis*-f



(215) Hawaii 50–*Cyrtandra nanawaleensis*-f (562 ac; 227 ha). See paragraph (k)(214)(ii) of this section for the map of this unit.

(216) Hawaii 51–*Cyanea tritomantha*-i (17,774 ac; 7,193 ha).

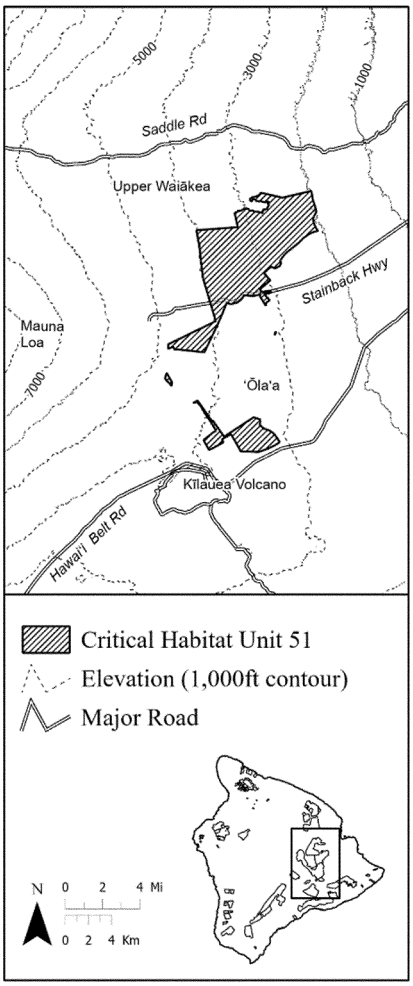
(i) This unit is also critical habitat for Hawaii 51–*Phyllostegia floribunda*-s, Hawaii 51–*Pittosporum hawaiiense*-u, Hawaii 51–*Schiedea diffusa* ssp. *macraei*-s, and Hawaii 51–*Stenogyne cranwelliae*-s (see paragraphs (k)(217), (k)(218), (k)(219), and (k)(220), respectively, of this section).

(ii) Map 118 follows:

Figure 126 to paragraph (k)

Map 118

Hawaii 51–*Cyanea tritomantha*-i, Hawaii 51–*Phyllostegia floribunda*-s, Hawaii 51–*Pittosporum hawaiiense*-u, Hawaii 51–*Schiedea diffusa* ssp. *macraei*-s, Hawaii 51–*Stenogyne cranwelliae*-s



(217) Hawaii 51–*Phyllostegia floribunda*-s (17,774 ac; 7,193 ha). See paragraph (k)(216)(ii) of this section for the map of this unit.

(218) Hawaii 51–*Pittosporum hawaiiense*-u (17,774 ac; 7,193 ha). See paragraph (k)(216)(ii) of this section for the map of this unit.

(219) Hawaii 51–*Schiedea diffusa* ssp. *macraei*-s (17,774 ac; 7,193 ha). See paragraph (k)(216)(ii) of this section for the map of this unit.

(220) Hawaii 51–*Stenogyne cranwelliae*-s (17,774 ac; 7,193 ha). See paragraph (k)(216)(ii) of this section for the map of this unit.

(221) Hawaii 52–*Cyanea tritomantha*-j (3,656 ac; 1,479 ha).

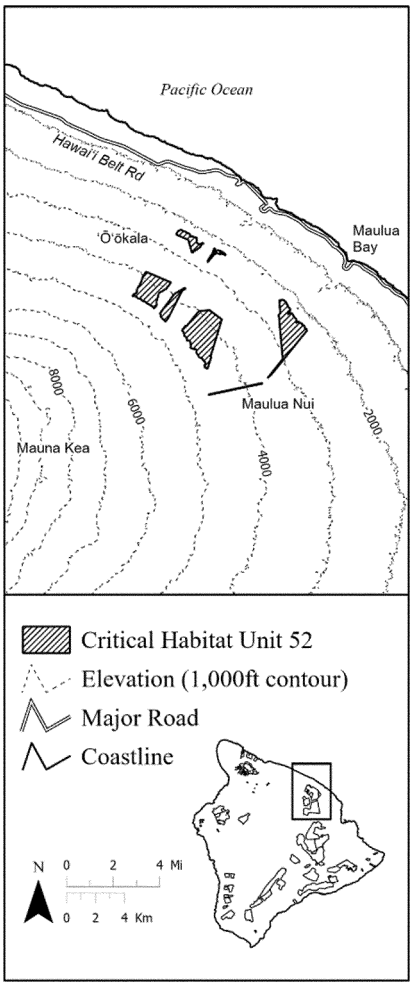
(i) This unit is also critical habitat for Hawaii 52–*Cyrtandra wagneri*-b, Hawaii 52–*Melicope remyi*-d, Hawaii 52–*Phyllostegia floribunda*-t, Hawaii 52–*Pittosporum hawaiiense*-v, Hawaii 52–*Schiedea diffusa* ssp. *macraei*-t, and Hawaii 52–*Stenogyne cranwelliae*-t (see paragraphs (k)(222), (k)(223), (k)(224), (k)(225), (k)(226), and (k)(227), respectively, of this section).

(ii) Map 119 follows:

Figure 127 to paragraph (k)

Map 119

Hawaii 52–*Cyanea tritomantha*-j, Hawaii 52–*Cyrtandra wagneri*-b, Hawaii 52–*Melicope remyi*-d, Hawaii 52–*Phyllostegia floribunda*-t, Hawaii 52–*Pittosporum hawaiiense*-v, Hawaii 52–*Schiedea diffusa* ssp. *macraei*-t, Hawaii 52–*Stenogyne cranwelliae*-t



(222) Hawaii 52–*Cyrtandra wagneri*-b (3,656 ac; 1,479 ha). See paragraph (k)(221)(ii) of this section for the map of this unit.

(223) Hawaii 52–*Melicope remyi*-d (3,656 ac; 1,479 ha). See paragraph (k)(221)(ii) of this section for the map of this unit.

(224) Hawaii 52–*Phyllostegia floribunda*-t (3,656 ac; 1,479 ha). See paragraph (k)(221)(ii) of this section for the map of this unit.

(225) Hawaii 52–*Pittosporum hawaiiense*-v (3,656 ac; 1,479 ha). See paragraph (k)(221)(ii) of this section for the map of this unit.

(226) Hawaii 52–*Schiedea diffusa* ssp. *macraei*-t (3,656 ac; 1,479 ha). See paragraph (k)(221)(ii) of this section for the map of this unit.

(227) Hawaii 52–*Stenogyne cranwelliae*-t (3,656 ac; 1,479 ha). See paragraph (k)(221)(ii) of this section for the map of this unit.

(228) Hawaii 53–*Bidens hillebrandiana* ssp. *hillebrandiana*-b (154 ac; 62 ha)

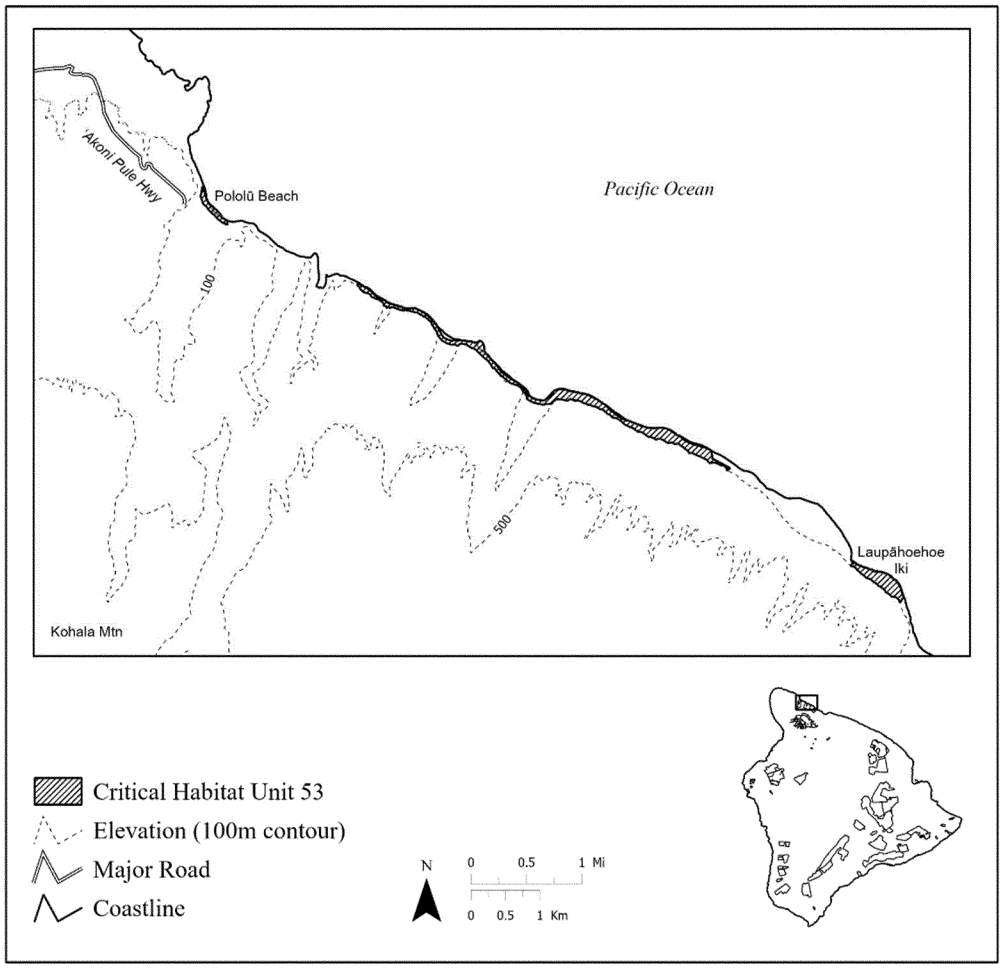
(i) [Reserved].

(ii) Map 120 follows:

Figure 128 to paragraph (k)

Map 120

Hawaii 53–*Bidens hillebrandiana* ssp. *hillebrandiana*-b


'Akoni Pule Hwy
Pololū Beach
Pacific Ocean
100
500
Laupāhoehoe Iki
Kohala Mtn
Critical Habitat Unit 53
Elevation (100m contour)
Major Road
Coastline
N
0 0.5 1 Mi
0 0.5 1 Km

(229) Hawaii 54–*Cyanea tritomantha*-k (5,945 ac; 2,406 ha).

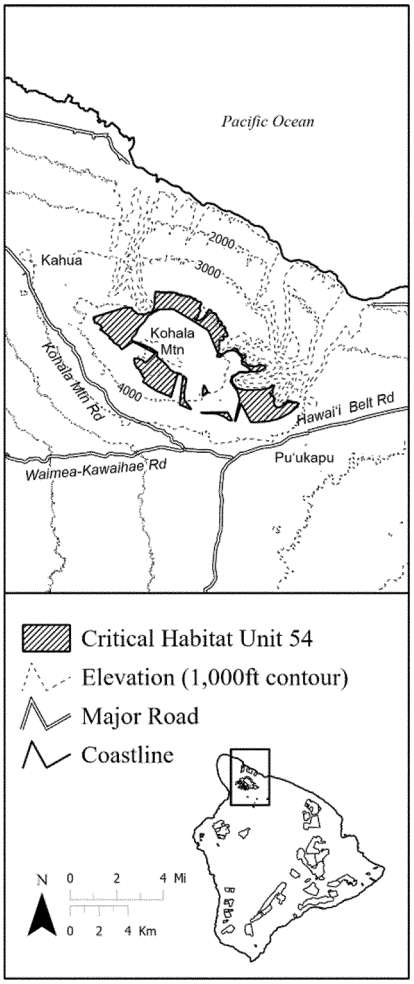
(i) This unit is also critical habitat for Hawaii 54–*Melicope remyi*-e, Hawaii 54–*Phyllostegia floribunda*-u, Hawaii 54–*Pittosporum hawaiiense*-w, Hawaii 54–*Schiedea diffusa* ssp. *macraei*-u, and Hawaii 54–*Stenogyne cranwelliae*-u (see paragraphs (k)(230), (k)(231), (k)(232), (k)(233), and (k)(234), respectively, of this section).

(ii) Map 121 follows:

Figure 129 to paragraph (k)

Map 121

Hawaii 54–*Cyanea tritomantha*-k, Hawaii 54–*Melicope remyi*-e, Hawaii 54–*Phyllostegia floribunda*-u, Hawaii 54–*Pittosporum hawaiiense*-w, Hawaii 54–*Schiedea diffusa* ssp. *macraei*-u, Hawaii 54–*Stenogyne cranwelliae*-u



(230) Hawaii 54–*Melicope remyi*-e (5,945 ac; 2,406 ha). See paragraph (k)(229)(ii) of this section for the map of this unit.

(231) Hawaii 54–*Phyllostegia floribunda*-u (5,945 ac; 2,406 ha). See paragraph (k)(229)(ii) of this section for the map of this unit.

(232) Hawaii 54–*Pittosporum hawaiiense*-w (5,945 ac; 2,406 ha). See paragraph (k)(229)(ii) of this section for the map of this unit.

(233) Hawaii 54–*Schiedea diffusa* ssp. *macraei*-u (5,945 ac; 2,406 ha). See paragraph (k)(229)(ii) of this section for the map of this unit.

(234) Hawaii 54–*Stenogyne cranwelliae*-u (5,945 ac; 2,406 ha). See paragraph (k)(229)(ii) of this section for the map of this unit.

(235) Hawaii 55–*Schiedea hawaiiensis*-a (6,822 ac; 2,761 ha)

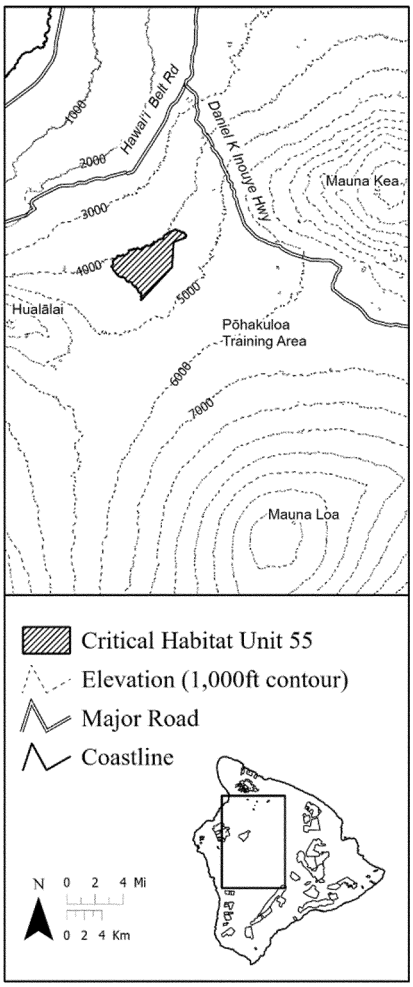
(i) [Reserved].

(ii) Map 122 follows:

Figure 130 to paragraph (k)

Map 122

Hawaii 55–*Schiedea hawaiiensis*-a



(236) Hawaii 56–*Cyanea marksii*-i (224 ac; 91 ha)

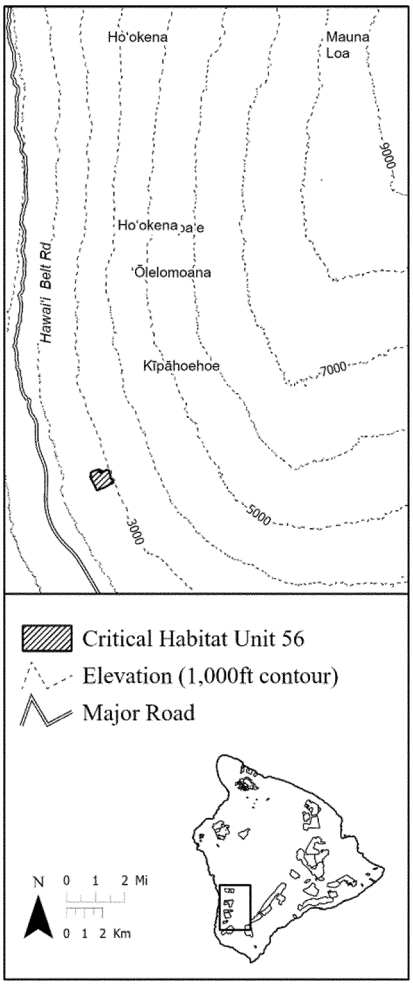
(i) This unit is also critical habitat for Hawaii 56–*Schiedea diffusa* ssp. *macraei*-v (see paragraph (k)(237) of this section).

(ii) Map 123 follows:

Figure 131 to paragraph (k)

Map 123

Hawaii 56–*Cyanea marksii*-i, Hawaii 56–*Schiedea diffusa* ssp. *macraei*-v



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(237) Hawaii 56–*Schiedea diffusa* ssp. *macraei*-v (224 ac; 91 ha). See paragraph (k)(236)(ii) of this section for the map of this unit.

(238) Table of Listed Species Within Each Critical Habitat Unit for the Island of Hawaii.

Unit name	Species occupied	Species unoccupied
Hawaii 1—*Clermontia lindseyana*-a	*Clermontia lindseyana*	*Clermontia lindseyana*.
Hawaii 1—*Clermontia peleana*-a	*Clermontia peleana*	*Clermontia peleana*.

Unit name	Species occupied	Species unoccupied
Hawaii 1—*Clermontia pyrularia*-a		*Clermontia pyrularia*.
Hawaii 1—*Cyanea shipmanii*-a	*Cyanea shipmanii*	*Cyanea shipmanii*.
Hawaii 1—*Phyllostegia racemosa*-a	*Phyllostegia racemosa*	*Phyllostegia racemosa*.
Hawaii 2—*Clermontia lindseyana*-b	*Clermontia lindseyana*	*Clermontia lindseyana*.
Hawaii 2—*Clermontia pyrularia*-b	*Clermontia pyrularia*	*Clermontia pyrularia*.
Hawaii 2—*Phyllostegia racemosa*-b	*Phyllostegia racemosa*	*Phyllostegia racemosa*.
Hawaii 3—*Clermontia peleana*-b	*Clermontia peleana*	*Clermontia peleana*.
Hawaii 3—*Cyanea platyphylla*-a	*Cyanea platyphylla*	*Cyanea platyphylla*.
Hawaii 3—*Cyanea tritomantha*-a	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 3—*Cyrtandra giffardii*-a	*Cyrtandra giffardii*	*Cyrtandra giffardii*.
Hawaii 3—*Cyrtandra tintinnabula*-a	*Cyrtandra tintinnabula*	*Cyrtandra tintinnabula*.
Hawaii 3—*Cyrtandra wagneri*-a	*Cyrtandra wagneri*	*Cyrtandra wagneri*.
Hawaii 3—*Melicope remyi*-a	*Melicope remyi*	*Melicope remyi*.
Hawaii 3—*Phyllostegia floribunda*-a	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 3—*Phyllostegia warshaueri*-a	*Phyllostegia warshaueri*	*Phyllostegia warshaueri*.
Hawaii 3—*Pittosporum hawaiiense*-a		*Pittosporum hawaiiense*.
Hawaii 3—*Schiedea diffusa* ssp. *macraei*-a		*Schiedea diffusa* ssp. *macraei*.
Hawaii 3—*Stenogyne cranwelliae*-a	*Stenogyne cranwelliae*	*Stenogyne cranwelliae*.
Hawaii 4—*Isodendrion hosakae*-a		*Isodendrion hosakae*.
Hawaii 4—*Isodendrion hosakae*-b		*Isodendrion hosakae*.
Hawaii 4—*Isodendrion hosakae*-c		*Isodendrion hosakae*.
Hawaii 4—*Isodendrion hosakae*-d		*Isodendrion hosakae*.
Hawaii 4—*Isodendrion hosakae*-e		*Isodendrion hosakae*.
Hawaii 4—*Isodendrion hosakae*-f	*Isodendrion hosakae*	*Isodendrion hosakae*.
Hawaii 4—*Vigna o-wahuensis*-a		*Vigna o-wahuensi*..
Hawaii 4—*Vigna o-wahuensis*-b		*Vigna o-wahuensis*.
Hawaii 4—*Vigna o-wahuensis*-c		*Vigna o-wahuensis*.
Hawaii 5—*Nothocestrum breviflorum*-a		*Nothocestrum breviflorum*.
Hawaii 6—*Bidens hillebrandiana* ssp. *hillebrandiana*-a.	*Bidens hillebrandiana* ssp. *hillebrandiana*	*Bidens hillebrandiana* ssp. *hillebrandiana*.
Hawaii 6—*Nothocestrum breviflorum*-b	*Nothocestrum breviflorum*	*Nothocestrum breviflorum*.
Hawaii 7—*Dracaena konaensis*-a	*Dracaena konaensis*	*Dracaena konaensis*.
Hawaii 8—*Clermontia drepanomorpha*-a	*Clermontia drepanomorpha*	*Clermontia drepanomorpha*.
Hawaii 8—*Cyanea tritomantha*-b	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 8—*Melicope remyi*-b		*Melicope remyi*.
Hawaii 8—*Phyllostegia floribunda*-b		*Phyllostegia floribunda*.
Hawaii 8—*Phyllostegia warshaueri*-b	*Phyllostegia warshaueri*	*Phyllostegia warshaueri*.
Hawaii 8—*Pittosporum hawaiiense*-b	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 8—*Schiedea diffusa* ssp. *macraei*-b	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 8—*Stenogyne cranwelliae*-b	*Stenogyne cranwelliae*	*Stenogyne cranwelliae*.
Hawaii 9—*Achyranthes mutica*-a		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-b	*Achyranthes mutica*	*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-c		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-d		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-e		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-f		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-g		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-h		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-i		*Achyranthes mutica*.
Hawaii 9—*Achyranthes mutica*-j		*Achyranthes mutica*.
Hawaii 9—*Cyanea tritomantha*-c	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 9—*Melicope remyi*-c		*Melicope remyi*.
Hawaii 9—*Phyllostegia floribunda*-c		*Phyllostegia floribunda*.
Hawaii 9—*Pittosporum hawaiiense*-c	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 9—*Schiedea diffusa* ssp. *macraei*-c	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 9—*Stenogyne cranwelliae*-c	*Stenogyne cranwelliae*	*Stenogyne cranwelliae*.
Hawaii 10—*Argyroxiphium kauense*-a		*Argyroxiphium kauense*.
Hawaii 10—*Bidens micrantha* ssp. *ctenophylla*-a.		*Bidens micrantha* ssp. *ctenophylla*.
Hawaii 10—*Bonamia menziesii*-a		*Bonamia menziesii*.
Hawaii 10—*Colubrina oppositifolia*-a	*Colubrina oppositifolia*	*Colubrina oppositifolia*.
Hawaii 10—*Delissea undulata*-a		*Delissea undulata*.
Hawaii 10—*Delissea undulata*-b	*Delissea undulata*	*Delissea undulata*.
Hawaii 10—*Dracaena konaensis*-b	*Dracaena konaensis*	*Dracaena konaensis*.
Hawaii 10—*Hibiscadelphus hualalaiensis*-a	*Hibiscadelphus hualalaiensis*	*Hibiscadelphus hualalaiensis*.
Hawaii 10—*Hibiscus brackenridgei*-a	*Hibiscus brackenridgei*	*Hibiscus brackenridgei*.
Hawaii 10—*Isodendrion pyrifolium*-a		*Isodendrion pyrifolium*.
Hawaii 10—*Mezoneuron kavaiense*-a	*Mezoneuron kavaiense*	*Mezoneuron kavaiense*.
Hawaii 10—*Neraudia ovata*-a		*Neraudia ovata*.
Hawaii 10—*Nothocestrum breviflorum*-c	*Nothocestrum breviflorum*	*Nothocestrum breviflorum*.
Hawaii 10—*Solanum incompletum*-a		*Solanum incompletum*.
Hawaii 10—*Zanthoxylum dipetalum* ssp. *tomentosum*-a.	*Zanthoxylum dipetalum* ssp. *tomentosum*	*Zanthoxylum dipetalum* ssp. *tomentosum*.
Hawaii 11—*Cyanea hamatiflora* ssp. *carlsonii*-a	*Cyanea hamatiflora* ssp. *carlsonii*	*Cyanea hamatiflora* ssp. *carlsonii*.

Unit name	Species occupied	Species unoccupied
Hawaii 11—*Solanum incompletum*-b		*Solanum incompletum*.
Hawaii 14—*Cyanea hamatiflora* ssp. *carlsonii*-b		*Cyanea hamatiflora* ssp. *carlsonii*.
Hawaii 15—*Cyanea hamatiflora* ssp. *carlsonii*-c		*Cyanea hamatiflora* ssp. *carlsonii*.
Hawaii 15—*Cyanea marksii*-a Section 4	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 15—*Cyanea marksii*-b—Section 5	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 15—*Cyanea stictophylla*-a	*Cyanea stictophylla*	*Cyanea stictophylla*.
Hawaii 15—*Phyllostegia floribunda*-d—Section 4.	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 15—*Phyllostegia floribunda*-e—Section 5.		*Phyllostegia floribunda*.
Hawaii 15—*Pittosporum hawaiiense*-d—Section 4.	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 15—*Pittosporum hawaiiense*-e—Section 5.		*Pittosporum hawaiiense*.
Hawaii 15—*Schiedea diffusa* ssp. *macraei*-d—Section 4.		*Schiedea diffusa* ssp. *macraei*.
Hawaii 15—*Schiedea diffusa* ssp. *macraei*-e—Section 5.		*Schiedea diffusa* ssp. *macraei*.
Hawaii 15—*Stenogyne cranwelliae*-d—Section 4.		*Stenogyne cranwelliae*.
Hawaii 15—*Stenogyne cranwelliae*-e—Section 5.		*Stenogyne cranwelliae*.
Hawaii 16—*Cyanea hamatiflora* ssp. *carlsonii*-d	*Cyanea hamatiflora* ssp. *carlsonii*	*Cyanea hamatiflora* ssp. *carlsonii*.
Hawaii 16—*Cyanea marksii*-c	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 16—*Cyanea stictophylla*-b	*Cyanea stictophylla*	*Cyanea stictophylla*.
Hawaii 16—*Phyllostegia floribunda*-f	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 16—*Pittosporum hawaiiense*-f		*Pittosporum hawaiiense*.
Hawaii 16—*Schiedea diffusa* ssp. *macraei*-f		*Schiedea diffusa* ssp. *macraei*.
Hawaii 16—*Stenogyne cranwelliae*-f		*Stenogyne cranwelliae*.
Hawaii 17—*Asplenium dielerectum*-a	*Asplenium dielerectum*	*Asplenium dielerectum*.
Hawaii 17—*Flueggea neowawraea*-a	*Flueggea neowawraea*	*Flueggea neowawraea*.
Hawaii 18—*Asplenium dielerectum*-b	*Asplenium dielerectum*	*Asplenium dielerectum*.
Hawaii 18—*Colubrina oppositifolia*-b	*Colubrina oppositifolia*	*Colubrina oppositifolia*.
Hawaii 18—*Dracaena konaensis*-c	*Dracaena konaensis*	*Dracaena konaensis*.
Hawaii 18—*Flueggea neowawraea*-b	*Flueggea neowawraea*	*Flueggea neowawraea*.
Hawaii 18—*Gouania vitifolia*-a	*Gouania vitifolia*	*Gouania vitifolia*.
Hawaii 18—*Neraudia ovata*-d	*Neraudia ovata*	*Neraudia ovata*.
Hawaii 19—*Mariscus fauriei*-a	*Mariscus fauriei*	*Mariscus fauriei*.
Hawaii 20—*Sesbania tomentosa*-a	*Sesbania tomentosa*	*Sesbania tomentosa*.
Hawaii 21—*Ischaemum byrone*-a		*Ischaemum byrone*.
Hawaii 22—*Ischaemum byrone*-b	*Ischaemum byrone*	*Ischaemum byrone*.
Hawaii 23—*Dracaena konaensis*-d	*Dracaena konaensis*	*Dracaena konaensis*.
Hawaii 23—*Phyllostegia floribunda*-g	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 23—*Pittosporum hawaiiense*-g	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 23—*Sesbania tomentosa*-b	*Sesbania tomentosa*	*Sesbania tomentosa*.
Hawaii 24—*Argyroxiphium kauense*-b	*Argyroxiphium kauense*	*Argyroxiphium kauense*.
Hawaii 24—*Asplenium fragile* var. *insulare*-a	*Asplenium fragile* var. *insulare*	*Asplenium fragile* var. *insulare*..
Hawaii 24—*Cyanea stictophylla*-c		*Cyanea stictophylla*.
Hawaii 24—*Cyanea tritomantha*-d—Section 8	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 24—*Melicope zahlbruckneri*-a		*Melicope zahlbruckneri*.
Hawaii 24—*Phyllostegia velutina*-a	*Phyllostegia velutina*	*Phyllostegia velutina*.
Hawaii 24—*Pittosporum hawaiiense*-h—Section 8.	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 24—*Pittosporum hawaiiense*-i—Section 9.	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 24—*Plantago hawaiensis*-a	*Plantago hawaiensis*	*Plantago hawaiensis*.
Hawaii 24—*Schiedea diffusa* ssp. *macraei*-g—Section 8.	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 24—*Schiedea diffusa* ssp. *macraei*-h—Section 9.	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 24—*Stenogyne cranwelliae*-g—Section 8.		*Stenogyne cranwelliae*.
Hawaii 24—*Stenogyne cranwelliae*-h—Section 9.		*Stenogyne cranwelliae*.
Hawaii 25—*Argyroxiphium kauense*-c	*Argyroxiphium kauense*	*Argyroxiphium kauense*.
Hawaii 25—*Plantago hawaiensis*-b	*Plantago hawaiensis*	*Plantago hawaiensis*.
Hawaii 25—*Silene hawaiiensis*-a	*Silene hawaiiensis*	*Silene hawaiiensis*.
Hawaii 26—*Hibiscadelphus giffardianus*-a	*Hibiscadelphus giffardianus*	*Hibiscadelphus giffardianus*.
Hawaii 26—*Melicope zahlbruckneri*-b	*Melicope zahlbruckneri*	*Melicope zahlbruckneri*.
Hawaii 27—*Portulaca sclerocarpa*-a	*Portulaca sclerocarpa*	*Portulaca sclerocarpa*.
Hawaii 27—*Silene hawaiiensis*-b	*Silene hawaiiensis*	*Silene hawaiiensis*.
Hawaii 28—*Adenophorus periens*-a	*Adenophorus periens*	*Adenophorus periens*.
Hawaii 28—*Cyrtandra nanawaleensis*-a	*Cyrtandra nanawaleensis*	*Cyrtandra nanawaleensis*.
Hawaii 28—*Phyllostegia floribunda*-h	*Phyllostegia floribunda*	*Phyllostegia floribunda*.

Unit name	Species occupied	Species unoccupied
Hawaii 29—*Clermontia peleana*-c	*Clermontia peleana*	*Clermontia peleana*.
Hawaii 29—*Cyanea platyphylla*-b	*Cyanea platyphylla*	*Cyanea platyphylla*.
Hawaii 29—*Cyanea tritomantha*-e	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 29—*Cyrtandra giffardii*-b		*Cyrtandra giffardii*.
Hawaii 29—*Cyrtandra tintinnabula*-b		*Cyrtandra tintinnabula*.
Hawaii 29—*Phyllostegia floribunda*-i	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 29—*Pittosporum hawaiiense*-j	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 29—*Schiedea diffusa* ssp. *macraei*-i	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 29—*Stenogyne cranwelliae*-i		*Stenogyne cranwelliae*.
Hawaii 30—*Argyroxiphium kauense*-d	*Argyroxiphium kauense*	*Argyroxiphium kauense*.
Hawaii 30—*Clermontia lindseyana*-c	*Clermontia lindseyana*	*Clermontia lindseyana*.
Hawaii 30—*Cyanea shipmanii*-b	*Cyanea shipmanii*	*Cyanea shipmanii*.
Hawaii 30—*Cyanea shipmanii*-c		*Cyanea shipmanii*.
Hawaii 30—*Cyanea stictophylla*-d		*Cyanea stictophylla*.
Hawaii 30—*Cyanea tritomantha*-f	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 30—*Cyrtandra giffardii*-c	*Cyrtandra giffardii*	*Cyrtandra giffardii*.
Hawaii 30—*Phyllostegia floribunda*-j	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 30—*Phyllostegia racemosa*-c		*Phyllostegia racemosa*.
Hawaii 30—*Phyllostegia velutina*-b	*Phyllostegia velutina*	*Phyllostegia velutina*.
Hawaii 30—*Pittosporum hawaiiense*-k	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 30—*Plantago hawaiensis*-c	*Plantago hawaiensis*	*Plantago hawaiensis*.
Hawaii 30—*Schiedea diffusa* ssp. *macraei*-j	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 30—*Sicyos alba*-a	*Sicyos alba*	*Sicyos alba*.
Hawaii 30—*Stenogyne cranwelliae*-j		*Stenogyne cranwelliae*.
Hawaii 31—*Bidens micrantha* ssp. *ctenophylla*-b.		*Bidens micrantha* ssp. *ctenophylla*.
Hawaii 31—*Isodendrion pyrifolium*-b		*Isodendrion pyrifolium*.
Hawaii 31—*Mezoneuron kavaiense*-b	*Mezoneuron kavaiense*	*Mezoneuron kavaiense*.
Hawaii 33—*Bidens micrantha* ssp. *ctenophylla*-d.		*Bidens micrantha* ssp. *ctenophylla*.
Hawaii 33—*Isodendrion pyrifolium*-d		*Isodendrion pyrifolium*.
Hawaii 33—*Mezoneuron kavaiense*-d		*Mezoneuron kavaiense*.
Hawaii 34—*Bidens micrantha* ssp. *ctenophylla*-e.		*Bidens micrantha* ssp. *ctenophylla*.
Hawaii 34—*Isodendrion pyrifolium*-e		*Isodendrion pyrifolium*.
Hawaii 34—*Mezoneuron kavaiense*-e		*Mezoneuron kavaiense*.
Hawaii 36—*Bidens micrantha* ssp. *ctenophylla*-g.	*Bidens micrantha* ssp. *ctenophylla*	*Bidens micrantha* ssp. *ctenophylla*.
Hawaii 36—*Isodendrion pyrifolium*-g		*Isodendrion pyrifolium*.
Hawaii 37—*Cyanea marksii*-d	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 37—*Phyllostegia floribunda*-k		*Phyllostegia floribunda*.
Hawaii 37—*Pittosporum hawaiiense*-l		*Pittosporum hawaiiense*.
Hawaii 37—*Schiedea diffusa* ssp. *macraei*-k		*Schiedea diffusa* ssp. *macraei*.
Hawaii 37—*Stenogyne cranwelliae*-k		*Stenogyne cranwelliae*.
Hawaii 38—*Cyanea marksii*-e	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 38—*Phyllostegia floribunda*-l		*Phyllostegia floribunda*.
Hawaii 38—*Pittosporum hawaiiense*-m		*Pittosporum hawaiiense*.
Hawaii 38—*Schiedea diffusa* ssp. *macraei*-l		*Schiedea diffusa* ssp. *macraei*.
Hawaii 38—*Stenogyne cranwelliae*-l		*Stenogyne cranwelliae*.
Hawaii 39—*Cyanea marksii*-f	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 39—*Phyllostegia floribunda*-m	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 39—*Pittosporum hawaiiense*-n	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 39—*Schiedea diffusa* ssp. *macraei*-m		*Schiedea diffusa* ssp. *macrae*.
Hawaii 39—*Stenogyne cranwelliae*-m		*Stenogyne cranwelliae*.
Hawaii 40—*Cyanea marksii*-g	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 40—*Phyllostegia floribunda*-n	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 40—*Pittosporum hawaiiense*-o		*Pittosporum hawaiiense*.
Hawaii 40—*Schiedea diffusa* ssp. *macraei*-n		*Schiedea diffusa* ssp. *macraei*.
Hawaii 40—*Stenogyne cranwelliae*-n		*Stenogyne cranwelliae*.
Hawaii 41—*Cyanea marksii*-h	*Cyanea marksii*	*Cyanea marksii*.
Hawaii 41—*Phyllostegia floribunda*-o	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 41—*Pittosporum hawaiiense*-p	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 41—*Schiedea diffusa* ssp. *macraei*-o		*Schiedea diffusa* ssp. *macraei*.
Hawaii 41—*Stenogyne cranwelliae*-o		*Stenogyne cranwelliae*.
Hawaii 42—*Cyanea tritomantha*-g		*Cyanea tritomantha*.
Hawaii 42—*Phyllostegia floribunda*-p		*Phyllostegia floribunda*.
Hawaii 42—*Pittosporum hawaiiense*-q	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 42—*Schiedea diffusa* ssp. *macraei*-p	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macrae*..
Hawaii 42—*Stenogyne cranwelliae*-p		*Stenogyne cranwelliae*.
Hawaii 43—*Pittosporum hawaiiense*-r	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 43—*Schiedea diffusa* ssp. *macraei*-q	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macrae*..
Hawaii 43—*Stenogyne cranwelliae*-q		*Stenogyne cranwelliae*.
Hawaii 44—*Cyanea tritomantha*-h	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 44—*Pittosporum hawaiiense*-s	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.

Unit name	Species occupied	Species unoccupied
Hawaii 44—*Schiedea diffusa* ssp. *macraei*-r	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 44—*Stenogyne cranwelliae*-r		*Stenogyne cranwelliae*.
Hawaii 45—*Phyllostegia floribunda*-q	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 45—*Pittosporum hawaiiense*-t	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 46—*Cyrtandra nanawaleensis*-b	*Cyrtandra nanawaleensis*	*Cyrtandra nanawaleensis*.
Hawaii 46—*Phyllostegia floribunda*-r	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 47—*Cyrtandra nanawaleensis*-c	*Cyrtandra nanawaleensis*	*Cyrtandra nanawaleensis*.
Hawaii 48—*Cyrtandra nanawaleensis*-d	*Cyrtandra nanawaleensis*	*Cyrtandra nanawaleensis*.
Hawaii 49—*Cyrtandra nanawaleensis*-e	*Cyrtandra nanawaleensis*	*Cyrtandra nanawaleensis*.
Hawaii 50—*Cyrtandra nanawaleensis*-f	*Cyrtandra nanawaleensis*	*Cyrtandra nanawaleensis*..
Hawaii 51—*Cyanea tritomantha*-i	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 51—*Phyllostegia floribunda*-s	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 51—*Pittosporum hawaiiense*-u	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 51—*Schiedea diffusa* ssp. *macraei*-s	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 51—*Stenogyne cranwelliae*-s		*Stenogyne cranwelliae*.
Hawaii 52—*Cyanea tritomantha*-j	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 52—*Cyrtandra wagneri*-b	*Cyrtandra wagneri*	*Cyrtandra wagneri*.
Hawaii 52—*Melicope remyi*-d	*Melicope remyi*	*Melicope remyi*.
Hawaii 52—*Phyllostegia floribunda*-t	*Phyllostegia floribunda*	*Phyllostegia floribunda*.
Hawaii 52—*Pittosporum hawaiiense*-v		*Pittosporum hawaiiense*.
Hawaii 52—*Schiedea diffusa* ssp. *macraei*-t		*Schiedea diffusa* ssp. *macraei*.
Hawaii 52—*Stenogyne cranwelliae*-t	*Stenogyne cranwelliae*	*Stenogyne cranwelliae*.
Hawaii 53—*Bidens hillebrandiana* ssp. *hillebrandiana*-b.	*Bidens hillebrandiana* ssp. *hillebrandiana*	*Bidens hillebrandiana* ssp. *hillebrandiana*.
Hawaii 54—*Cyanea tritomantha*-k	*Cyanea tritomantha*	*Cyanea tritomantha*.
Hawaii 54—*Melicope remyi*-e		*Melicope remyi*.
Hawaii 54—*Phyllostegia floribunda*-u		*Phyllostegia floribunda*.
Hawaii 54—*Pittosporum hawaiiense*-w	*Pittosporum hawaiiense*	*Pittosporum hawaiiense*.
Hawaii 54—*Schiedea diffusa* ssp. *macraei*-u	*Schiedea diffusa* ssp. *macraei*	*Schiedea diffusa* ssp. *macraei*.
Hawaii 54—*Stenogyne cranwelliae*-u	*Stenogyne cranwelliae*	*Stenogyne cranwelliae*.
Hawaii 55—*Schiedea hawaiiensis*-a		*Schiedea hawaiiensis*.
Hawaii 56—*Cyanea marksii*-i		*Cyanea marksii*.
Hawaii 56—*Schiedea diffusa* ssp. *macraei*-v		*Schiedea diffusa* ssp. *macraei*

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(1) Plants on the island of Hawaii; Constituent elements.—(1) Flowering plants.

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Family Asteraceae: Bidens hillebrandiana ssp. hillebrandiana (KOOKOOLAU)

Hawaii 6—*Bidens hillebrandiana* ssp. *hillebrandiana*-a and Hawaii 53—*Bidens hillebrandiana* ssp. *hillebrandiana*-b, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Bidens hillebrandiana* ssp. *hillebrandiana* on Hawaii Island. In units Hawaii 6—*Bidens hillebrandiana* ssp. *hillebrandiana*-a and Hawaii 53—*Bidens hillebrandiana* ssp. *hillebrandiana*-b, the physical and biological features of critical habitat in coastal ecosystem are:

(i) Elevation: Less than 984feet (ft) (300 meters (m)).

(ii) Annual precipitation: Less than 47 inches (in) (120 centimeters (cm)) to greater than 98 in (250 cm).

(iii) Substrate: Well-drained talus, calcareous slopes, dunes.

(iv) Canopy contains one or more of the following native plant genera: *Diospyros, Metrosideros, Myoporum, Pritchardia.*

(v) Subcanopy contains one or more of the following native plant genera: *Chenopodium, Gossypium, Heliotropium, Santalum, Scaevola.*

(vi) Understory contains one or more of the following native plant genera: *Eragrostis, Sesuvium, Sida, Sporobolus.*

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Family Campanulaceae: Cyanea marksii (HAHA)

Hawaii 15—*Cyanea marksii*-a-Section 4, Hawaii 15—*Cyanea marksii*-b-Section 5, Hawaii 16—*Cyanea marksii*-c, Hawaii 37—*Cyanea marksii*-d, Hawaii 38—*Cyanea marksii*-e, Hawaii 39—*Cyanea marksii*-f, Hawaii 40—*Cyanea marksii*-g, Hawaii 41—*Cyanea marksii*-h, and Hawaii 56—*Cyanea marksii*-i, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Cyanea marksii* on Hawaii Island. In units Hawaii 15—*Cyanea marksii*-a-Section 4, Hawaii 15—*Cyanea marksii*-b-Section 5, Hawaii 16—*Cyanea marksii*-c, Hawaii 37—*Cyanea marksii*-d, Hawaii 38—*Cyanea marksii*-e, Hawaii 39—*Cyanea marksii*-f, Hawaii 40—*Cyanea marksii*-g, Hawaii 41—*Cyanea marksii*-h, and Hawaii 56—*Cyanea marksii*-i, the physical and biological features of critical habitat in wet forest ecosystem are:

(i) Elevation: Less than 7,218 ft (2,200 m).

(ii) Annual precipitation: Greater than 98 in (250 cm).

(iii) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(iv) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(v) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(vi) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

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Family Campanulaceae: Cyanea tritomantha (AKU)

Hawaii 3—*Cyanea tritomantha*-a, Hawaii 8—*Cyanea tritomantha*-b, Hawaii 9—*Cyanea tritomantha*-c, Hawaii 24—*Cyanea tritomantha*-d-Section 8, Hawaii 29—*Cyanea tritomantha*-e, Hawaii 30—*Cyanea tritomantha*-f, Hawaii 42—*Cyanea tritomantha*-g, Hawaii 44—*Cyanea*

tritomantha-h, Hawaii 51—*Cyanea tritomantha*-i, Hawaii 52—*Cyanea tritomantha*-j, and Hawaii 54—*Cyanea tritomantha*-k, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Cyanea tritomantha* on Hawaii Island.

(i) In units Hawaii 3—*Cyanea tritomantha*-a, Hawaii 24—*Cyanea tritomantha*-d-Section 8, Hawaii 29—*Cyanea tritomantha*-e, Hawaii 30—*Cyanea tritomantha*-f, Hawaii 42—*Cyanea tritomantha*-g, Hawaii 44—*Cyanea tritomantha*-h, Hawaii 51—*Cyanea tritomantha*-i, and Hawaii 52—*Cyanea tritomantha*-j, the physical and biological features of critical habitat in wet forest ecosystem are:

(A) Elevation: Less than 7,218 ft (2,200 m).

(B) Annual precipitation: Greater than 98 in (250 cm).

(C) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

(ii) In units Hawaii 8—*Cyanea tritomantha*-b, Hawaii 9—*Cyanea tritomantha*-c, and Hawaii 54—*Cyanea tritomantha*-k, the physical and biological features of critical habitat in wet forest ecosystem are those provided above in paragraphs (i)(A) through (F) of this entry, and in wet grassland and shrubland ecosystem are:

(A) Elevation: 656 to 2,953 ft (200 to 900 m).

(B) Annual precipitation: 98 to 197 in (250 to 500 cm).

(C) Substrate: Older, weathered soils to younger, rocky substrates.

(D) Canopy contains one or more of the following native plant genera: *Ilex, Kadua, Melicope, Metrosideros, Myrsine.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Dubautia, Freycinetia, Hydrangea, Lobelia, Pipturus, Touchardia, Urera, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Carex, Cladium, Deschampsia, Dicranopteris, Eragrostis, Peperomia, Phyllostegia, Scaevola.*

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Family Caryophyllaceae: Schiedea diffusa ssp. macraei (no common name)

Hawaii 3—*Schiedea diffusa* ssp. *macraei*-a, Hawaii 8—*Schiedea diffusa* ssp. *macraei*-b, Hawaii 9—*Schiedea diffusa* ssp. *macraei*-c, Hawaii 15—*Schiedea diffusa* ssp. *macraei*-d-Section 4, Hawaii 15—*Schiedea diffusa* ssp. *macraei*-e-Section 5, Hawaii 16—*Schiedea diffusa* ssp. *macraei*-f, Hawaii 24—*Schiedea diffusa* ssp. *macraei*-g-Section 8, Hawaii 24—*Schiedea diffusa* ssp. *macraei*-h-Section 9, Hawaii 29—*Schiedea diffusa* ssp. *macraei*-i, Hawaii 30—*Schiedea diffusa* ssp. *macraei*-j, Hawaii 37—*Schiedea diffusa* ssp. *macraei*-k, Hawaii 38—*Schiedea diffusa* ssp. *macraei*-l, Hawaii 39—*Schiedea diffusa* ssp. *macraei*-m, Hawaii 40—*Schiedea diffusa* ssp. *macraei*-n, Hawaii 41—*Schiedea diffusa* ssp. *macraei*-o, Hawaii 42—*Schiedea diffusa* ssp. *macraei*-p, Hawaii 43—*Schiedea diffusa* ssp. *macraei*-q, Hawaii 44—*Schiedea diffusa* ssp. *macraei*-r, Hawaii 51—*Schiedea diffusa* ssp. *macraei*-s, Hawaii 52—*Schiedea diffusa* ssp. *macraei*-t, Hawaii 54—*Schiedea diffusa* ssp. *macraei*-u, and Hawaii 56—*Schiedea diffusa* ssp. *macraei*-v, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Schiedea diffusa* ssp. *macraei* on Hawaii Island. In units Hawaii 3—*Schiedea diffusa* ssp. *macraei*-a, Hawaii 8—*Schiedea diffusa* ssp. *macraei*-b, Hawaii 9—*Schiedea diffusa* ssp. *macraei*-c, Hawaii 15—*Schiedea diffusa* ssp. *macraei*-d-Section 4, Hawaii 15—*Schiedea diffusa* ssp. *macraei*-e-Section 5, Hawaii 16—*Schiedea diffusa* ssp. *macraei*-f, Hawaii 24—*Schiedea diffusa* ssp. *macraei*-g-Section 8, Hawaii 24—*Schiedea diffusa* ssp. *macraei*-h-Section 9, Hawaii 29—*Schiedea diffusa* ssp. *macraei*-i, Hawaii 30—*Schiedea diffusa* ssp. *macraei*-j, Hawaii 37—*Schiedea diffusa* ssp. *macraei*-k, Hawaii 38—*Schiedea diffusa* ssp. *macraei*-l, Hawaii 39—*Schiedea diffusa* ssp. *macraei*-m, Hawaii 40—*Schiedea diffusa* ssp. *macraei*-n, Hawaii 41—*Schiedea diffusa* ssp. *macraei*-o, Hawaii 42—*Schiedea diffusa* ssp. *macraei*-p, Hawaii 43—*Schiedea diffusa* ssp. *macraei*-q, Hawaii 44—*Schiedea diffusa* ssp. *macraei*-r, Hawaii 51—*Schiedea diffusa* ssp. *macraei*-s, Hawaii 52—*Schiedea diffusa* ssp. *macraei*-t, Hawaii 54—*Schiedea diffusa* ssp. *macraei*-u, and Hawaii 56—*Schiedea diffusa* ssp. *macraei*-v, the physical and biological features of critical habitat in wet forest ecosystem are:

(i) Elevation: Less than 7,218 ft (2,200 m).

(ii) Annual precipitation: Greater than 98 in (250 cm).

(iii) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(iv) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(v) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(vi) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

* * * * *

Family Caryophyllaceae: Schiedea hawaiiensis (MAOLIOLI)

Hawaii 55—*Schiedea hawaiiensis*-a, identified in the legal descriptions in paragraph (k) of this section, constitutes critical habitat for *Schiedea hawaiiensis* on Hawaii Island. In unit Hawaii 55—*Schiedea hawaiiensis*-a, the physical and biological features of critical habitat in dry forest ecosystem are:

(i) Elevation: Less than 9,500 ft (2,900 m).

(ii) Annual precipitation: Less than 79 in (200 cm).

(iii) Substrate: Well-drained, sandy loams or loams from volcanic ash or cinder; weathered basaltic lava.

(iv) Canopy contains one or more of the following native plant genera: *Acacia, Colubrina, Diospyros, Erythrina, Melicope, Metrosideros, Myoporum, Myrsine, Sophora.*

(v) Subcanopy contains one or more of the following native plant genera: *Achyranthes, Euphorbia, Leptecophylla, Nototrichium.*

(vi) Understory contains one or more of the following native plant genera: *Dodonaea, Doryopteris, Heteropogon, Pellaea.*

* * * * *

Family Gesneriaceae: Cyrtandra nanawaleensis (HAIWALE)

Hawaii 28—*Cyrtandra nanawaleensis*-a, Hawaii 46—*Cyrtandra nanawaleensis*-b, Hawaii 47—*Cyrtandra nanawaleensis*-c, Hawaii 48—*Cyrtandra nanawaleensis*-d, Hawaii 49—*Cyrtandra nanawaleensis*-e, and Hawaii 50—*Cyrtandra nanawaleensis*-f, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Cyrtandra nanawaleensis* on Hawaii Island.

(i) In units Hawaii 28—*Cyrtandra nanawaleensis*-a, Hawaii 46—*Cyrtandra nanawaleensis*-b, Hawaii 47—*Cyrtandra nanawaleensis*-c, and Hawaii 48—*Cyrtandra nanawaleensis*-d, the physical and biological features of critical habitat in wet forest ecosystem are:

(A) Elevation: Less than 7,218 ft (2,200 m).

(B) Annual precipitation: Greater than 98 in (250 cm).

(C) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

(ii) In units Hawaii 49—*Cyrtandra nanawaleensis*-e and Hawaii 50—*Cyrtandra nanawaleensis*-f, the physical and biological features of critical habitat in wet forest ecosystem are those provided above in paragraphs (i)(A) through (F) of this entry, and in the mesic forest ecosystem and mesic grassland and shrubland ecosystem are:

(A) Elevation: Less than 6,562 ft (2,000 m) in mesic forest ecosystem, and 98 to 7,546ft (30 to 2,300 m) in mesic grassland and shrubland ecosystem.

(B) Annual precipitation: 39 to 150 in (100 to 380 cm) in mesic forest ecosystem, and 39 to 98 in (100 to 250 cm) in mesic grassland and shrubland ecosystem.

(C) Substrate: Rocky, shallow, organic muck soils; rocky talus soils; shallow soils over weathered rock; deep soils over soft weathered rock; and gravelly alluvium in mesic forest ecosystem; and shallow soils that frequently dry with rocky outcrops in mesic grassland and shrubland ecosystem.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Charpentiera, Chrysodracon, Metrosideros, Myrsine, Nestegis, Pisonia, Santalum* in mesic forest ecosystem; and *Coprosma, Metrosideros, Wilkesia* in mesic grassland and shrubland ecosystem.

(E) Subcanopy contains one or more of the following native plant genera: *Coprosma, Freycinetia, Leptecophylla, Myoporum, Pipturus, Rubus, Sadleria, Sophora* in mesic forest ecosystem; and *Dodonaea, Dubautia, Leptecophylla, Osteomeles, Sadleria, Vaccinium* in mesic grassland and shrubland ecosystem.

(F) Understory contains one or more of the following native plant genera: *Ctenitis, Doodia, Dryopteris, Pelea, Sadleria* in mesic forest ecosystem; and *Bidens, Carex, Deschampsia, Dicranopteris, Dryopteris, Eragrostis, Euphorbia, Lipochaeta* in mesic grassland and shrubland ecosystem.

* * * * *

Family Gesneriaceae: Cyrtandra wagneri (HAIWALE)

Hawaii 3—*Cyrtandra wagneri*-a and Hawaii 52—*Cyrtandra wagneri*-b, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Cyrtandra wagneri* on Hawaii Island. In units Hawaii 3—*Cyrtandra wagneri*-a and Hawaii 52—*Cyrtandra wagneri*-b, the physical and biological features of critical habitat in wet forest ecosystem are:

(i) Elevation: Less than 7,218 ft (2,200 m).

(ii) Annual precipitation: Greater than 98 in (250 cm).

(iii) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(iv) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(v) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(vi) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

* * * * *

Family Lamiaceae: Phyllostegia floribunda (no common name)

Hawaii 3—*Phyllostegia floribunda*-a, Hawaii 8—*Phyllostegia floribund*a-b, Hawaii 9—*Phyllostegia floribunda*-c, Hawaii 15—*Phyllostegia floribunda*-d-Section 4, Hawaii 15—*Phyllostegia floribunda*-e-Section 5, Hawaii 16—*Phyllostegia floribunda*-f, Hawaii 23—*Phyllostegia floribunda*-g, Hawaii 28—*Phyllostegia floribunda*-h, Hawaii 29—*Phyllostegia floribunda*-i, Hawaii 30—*Phyllostegia floribunda*-j, Hawaii 37—*Phyllostegia floribunda*-k, Hawaii 38—*Phyllostegia floribunda*-l, Hawaii 39—*Phyllostegia floribunda*-m, Hawaii 40—*Phyllostegia floribunda*-n, Hawaii 41—*Phyllostegia floribunda*-o, Hawaii 42—*Phyllostegia floribunda*-p, Hawaii 45—*Phyllostegia floribunda*-q, Hawaii 46—*Phyllostegia floribunda*-r, Hawaii 51—*Phyllostegia floribunda*-s, Hawaii 52—*Phyllostegia floribunda*-t, and Hawaii 54—*Phyllostegia floribunda*-u, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Phyllostegia floribunda* on Hawaii Island.

(i) In units Hawaii 3—*Phyllostegia floribunda*-a, Hawaii 15—*Phyllostegia floribunda*-d-Section 4, Hawaii 15—*Phyllostegia floribunda*-e-Section 5, Hawaii 16—*Phyllostegia floribunda*-f, Hawaii 29—*Phyllostegia floribunda*-i, Hawaii 30—*Phyllostegia floribunda*-j, Hawaii 37—*Phyllostegia floribunda*-k, Hawaii 38—*Phyllostegia floribunda*-l, Hawaii 39—*Phyllostegia floribunda*-m, Hawaii 40—*Phyllostegia floribunda*-n, Hawaii 41—*Phyllostegia floribunda*-o, Hawaii 51—*Phyllostegia floribunda*-s, and Hawaii 52—*Phyllostegia floribunda*-t, the physical and biological features of critical habitat in wet forest ecosystem are:

(A) Elevation: Less than 7,218 ft (2,200 m).

(B) Annual precipitation: Greater than 98 in (250 cm).

(C) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

(ii) In units Hawaii 8—*Phyllostegia floribund*a-b, Hawaii 9—*Phyllostegia floribunda*-c, Hawaii 23—*Phyllostegia floribunda*-g, Hawaii 28—*Phyllostegia floribunda*-h, Hawaii 45—*Phyllostegia floribunda*-q, Hawaii 46—*Phyllostegia floribunda*-r, and Hawaii 54—*Phyllostegia floribunda*-u, the physical and biological features of critical habitat in wet forest ecosystem are those provided above in paragraphs (i)(A) through (F) of this entry, and in wet grassland and shrubland ecosystem are:

(A) Elevation: 656 to 2,953 ft (200 to 900 m).

(B) Annual precipitation: 98 to 197 in (250 to 500 cm).

(C) Substrate: Older, weathered soils to younger, rocky substrates.

(D) Canopy contains one or more of the following native plant genera: *Ilex, Kadua, Melicope, Metrosideros, Myrsine.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Dubautia, Freycinetia, Hydrangea, Lobelia, Pipturus, Touchardia, Urera, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Carex, Cladium, Deschampsia, Dicranopteris, Eragrostis, Peperomia, Phyllostegia, Scaevola.*

(iii) In unit Hawaii 42—*Phyllostegia floribunda*-p, the physical and biological features of critical habitat in wet forest ecosystem are those provided above in paragraphs (i)(A) through (F) of this entry, and in mesic forest ecosystem are:

(A) Elevation of less than 6,562 ft (2,000 m).

(B) Annual precipitation of 39 to 150 in (100 to 380 cm).

(C) Substrate of rocky, shallow, organic muck soils; rocky talus soils; shallow soils over weathered rock; deep soils over soft weathered rock; or gravelly alluvium.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Charpentiera, Chrysodracon, Metrosideros, Myrsine, Nestegis, Pisonia, Santalum.*

(E) Subcanopy contains one or more of the following native plant genera: *Coprosma, Freycinetia, Leptecophylla, Myoporum, Pipturus, Rubus, Sadleria, Sophora.*

(F) Understory contains one or more of the following native plant genera: *Ctenitis, Doodia, Dryopteris, Pelea, Sadleria.*

* * * * *

Family Lamiaceae: Stenogyne cranwelliae (no common name)

Hawaii 3—*Stenogyne cranwelliae*-a, Hawaii 8—*Stenogyne cranwelliae*-b, Hawaii 9—*Stenogyne cranwelliae*-c, Hawaii 15—*Stenogyne cranwelliae*-d-Section 4, Hawaii 15—*Stenogyne cranwelliae*-e-Section 5, Hawaii 16—*Stenogyne cranwelliae*-f, Hawaii 24—*Stenogyne cranwelliae*-g-Section 8, Hawaii 24—*Stenogyne cranwelliae*-h-Section 9, Hawaii 29—*Stenogyne cranwelliae*-i, Hawaii 30—*Stenogyne cranwelliae*-j, Hawaii 37—*Stenogyne cranwelliae*-k, Hawaii 38—*Stenogyne cranwelliae*-l, Hawaii 39—*Stenogyne cranwelliae*-m, Hawaii 40—*Stenogyne cranwelliae*-n, Hawaii 41—*Stenogyne cranwelliae*-o, Hawaii 42—*Stenogyne cranwelliae*-p, Hawaii 43—*Stenogyne cranwelliae*-q, Hawaii 44—*Stenogyne cranwelliae*-r, Hawaii 51—*Stenogyne cranwelliae*-s, Hawaii 52—*Stenogyne cranwelliae*-t, and Hawaii 54—*Stenogyne cranwelliae*-u, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Stenogyne cranwelliae* on Hawaii Island. In units Hawaii 3—*Stenogyne cranwelliae*-a, Hawaii 8—*Stenogyne cranwelliae*-b, Hawaii 9—*Stenogyne cranwelliae*-c, Hawaii 15—*Stenogyne cranwelliae*-d-Section 4, Hawaii 15—*Stenogyne cranwelliae*-e-Section 5, Hawaii 16—*Stenogyne cranwelliae*-f, Hawaii 24—*Stenogyne cranwelliae*-g-Section 8, Hawaii 24—*Stenogyne cranwelliae*-h-Section 9, Hawaii 29—*Stenogyne cranwelliae*-i, Hawaii 30—*Stenogyne cranwelliae*-j, Hawaii 37—*Stenogyne cranwelliae*-k, Hawaii 38—*Stenogyne cranwelliae*-l, Hawaii 39—*Stenogyne cranwelliae*-m, Hawaii 40—*Stenogyne cranwelliae*-n, Hawaii 41—*Stenogyne cranwelliae*-o, Hawaii 42—*Stenogyne cranwelliae*-p, Hawaii 43—*Stenogyne cranwelliae*-q, Hawaii 44—*Stenogyne cranwelliae*-r, Hawaii 51—*Stenogyne cranwelliae*-s, Hawaii 52—*Stenogyne cranwelliae*-t, and Hawaii 54—*Stenogyne cranwelliae*-u, the physical and biological features of critical habitat in wet forest ecosystem are:

(i) Elevation: Less than 7,218 ft (2,200 m).

(ii) Annual precipitation: Greater than 98 in (250 cm).

(iii) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(iv) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(v) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(vi) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

* * * * *

Family Pittosporaceae: Pittosporum hawaiiense (HOAWA, HAAWA)

Hawaii 3—*Pittosporum hawaiiense*-a, Hawaii 8—*Pittosporum hawaiiense*-b, Hawaii 9—*Pittosporum hawaiiense*-c, Hawaii 15—*Pittosporum hawaiiense*-d-Section 4, Hawaii 15—*Pittosporum hawaiiense*-e-Section 5, Hawaii 16—*Pittosporum hawaiiense*-f, Hawaii 23—*Pittosporum hawaiiense*-g, Hawaii 24—*Pittosporum hawaiiense*-h-Section 8, Hawaii 24—*Pittosporum hawaiiense*-i-Section 9, Hawaii 29—*Pittosporum hawaiiense*-j, Hawaii 30—*Pittosporum hawaiiense*-k, Hawaii 37—*Pittosporum hawaiiense*-l, Hawaii 38—*Pittosporum hawaiiense*-m, Hawaii 39—*Pittosporum hawaiiense*-n, Hawaii 40—*Pittosporum hawaiiense*-o, Hawaii 41—*Pittosporum hawaiiense*-p, Hawaii 42—*Pittosporum hawaiiense*-q, Hawaii 43—*Pittosporum hawaiiense*-r, Hawaii 44—*Pittosporum hawaiiense*-s, Hawaii 45—*Pittosporum hawaiiense*-t, Hawaii 51—*Pittosporum hawaiiense*-u, Hawaii 52—*Pittosporum hawaiiense*-v, and Hawaii 54—*Pittosporum hawaiiense*-w, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Pittosporum hawaiiense* on Hawaii Island.

(i) In units Hawaii 3—*Pittosporum hawaiiense*-a, Hawaii 8—*Pittosporum hawaiiense*-b, Hawaii 9—*Pittosporum hawaiiense*-c, Hawaii 15—*Pittosporum hawaiiense*-d-Section 4, Hawaii 15—*Pittosporum hawaiiense*-e-Section 5, Hawaii 16—*Pittosporum hawaiiense*-f, Hawaii 23—*Pittosporum hawaiiense*-g, Hawaii 29—*Pittosporum hawaiiense*-j, Hawaii 30—*Pittosporum hawaiiense*-k, Hawaii 37—*Pittosporum hawaiiense*-l, Hawaii 38—*Pittosporum hawaiiense*-m, Hawaii 39—*Pittosporum hawaiiense*-n, Hawaii 40—*Pittosporum hawaiiense*-o, Hawaii 41—*Pittosporum hawaiiense*-p, Hawaii 45—*Pittosporum hawaiiense*-t, Hawaii 51—*Pittosporum hawaiiense*-u, Hawaii 52—*Pittosporum hawaiiense*-v, and Hawaii 54—*Pittosporum hawaiiense*-w, the physical and biological features of critical habitat in wet forest ecosystem are:

(A) Elevation: Less than 7,218 ft (2,200 m).

(B) Annual precipitation: Greater than 98 in (250 cm).

(C) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(E) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(F) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

(ii) In units Hawaii 24—*Pittosporum hawaiiense*-h-Section 8, Hawaii 24—*Pittosporum hawaiiense*-i-Section 9, Hawaii 42—*Pittosporum hawaiiense*-q, Hawaii 43—*Pittosporum hawaiiense*-r, and Hawaii 44—*Pittosporum hawaiiense*-s, the physical and

biological features of critical habitat in wet forest ecosystem are those provided above in paragraphs (i)(A) through (F) of this entry, and in mesic forest ecosystem are:

(A) Elevation: Less than 6,562 ft (2,000 m).

(B) Annual precipitation: 39 to 150 in (100 to 380 cm).

(C) Substrate: Rocky, shallow, organic muck soils; rocky talus soils; shallow soils over weathered rock; deep soils over soft weathered rock; gravelly alluvium.

(D) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Charpentiera, Chrysodracon, Metrosideros, Myrsine, Nestegis, Pisonia, Santalum.*

(E) Subcanopy contains one or more of the following native plant genera: *Coprosma, Freycinetia, Leptecophylla, Myoporum, Pipturus, Rubus, Sadleria, Sophora.*

(F) Understory contains one or more of the following native plant genera: *Ctenitis, Doodia, Dryopteris, Pelea, Sadleria.*

* * * * *

Family Rutaceae: Melicope remyi (no common name)

Hawaii 3—*Melicope remyi*-a, Hawaii 8—*Melicope remyi*-b, Hawaii 9—*Melicope remyi*-c, Hawaii 52—*Melicope remyi*-d, and Hawaii 54—*Melicope remyi*-e, identified in the legal descriptions in paragraph (k) of this section, constitute critical habitat for *Melicope remyi* on Hawaii Island. In units Hawaii 3—*Melicope remyi*-a, Hawaii 8—*Melicope remyi*-b, Hawaii 9—*Melicope remyi*-c, Hawaii 52—*Melicope remyi*-d, and Hawaii 54—*Melicope remyi*-e, the physical and biological features of critical habitat in wet forest ecosystem are:

(i) Elevation: Less than 7,218 ft (2,200 m).

(ii) Annual precipitation: Greater than 98 in (250 cm).

(iii) Substrate: Very weathered soils to rocky substrate, basaltic lava, undeveloped soils, developed soils.

(iv) Canopy contains one or more of the following native plant genera: *Acacia, Antidesma, Cheirodendron, Ilex, Melicope, Metrosideros, Myrsine, Pittosporum, Psychotria.*

(v) Subcanopy contains one or more of the following native plant genera: *Cibotium, Clermontia, Coprosma, Cyanea, Freycinetia, Hydrangea, Vaccinium.*

(vi) Understory contains one or more of the following native plant genera: *Adenophorus, Cibotium, Cyrtandra, Dicranopteris, Huperzia, Peperomia, Stenogyne.*

* * * * *

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2024–04588 Filed 3–11–24; 8:45 am]

BILLING CODE 4333–15–P

FEDERAL REGISTER

Vol. 89 Tuesday,

No. 49 March 12, 2024

Part III

Commodity Futures Trading Commission

17 CFR Chapter I

Securities and Exchange Commission

17 CFR Parts 275 and 279

Form PF; Reporting Requirements for All Filers and Large Hedge Fund Advisers; Joint Final Rule

COMMODITY FUTURES TRADING COMMISSION

17 CFR Chapter I

RIN 3038–AF31

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 275 and 279

[Release No. IA–6546; File No. S7–22–22]

RIN 3235–AN13

Form PF; Reporting Requirements for All Filers and Large Hedge Fund Advisers

AGENCY: Commodity Futures Trading Commission and Securities and Exchange Commission.

ACTION: Joint final rule.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'') and the Securities and Exchange Commission (''SEC'') (collectively, ''we'' or ''Commissions'') are adopting amendments to Form PF, the confidential reporting form for certain SEC-registered investment advisers to private funds, including those that also are registered with the CFTC as a commodity pool operator (''CPO'') or commodity trading adviser (''CTA''). The amendments are designed to enhance the Financial Stability Oversight Council's (''FSOC's'') ability to monitor systemic risk as well as bolster the SEC's regulatory oversight of private fund advisers and investor protection efforts. In connection with the amendments to Form PF, the SEC is amending a rule under the Investment Advisers Act of 1940 (''Advisers Act'') to revise instructions for requesting a temporary hardship exemption.

DATES:

Effective date: This rule is effective March 12, 2025.

Compliance date: See section II.F of this final rule.

FOR FURTHER INFORMATION CONTACT: *CFTC:* Pamela Geraghty, Acting Deputy Director; Michael Ehrstein, Special Counsel; Elizabeth Groover, Special Counsel; or Andrew Ruggiero, Special Counsel, at (202) 418–6700, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. *SEC:* Neema Nassiri, Jill Pritzker, Senior Counsels; Tom Strumpf, Branch Chief; or Melissa Roverts Harke, Assistant Director, at (202) 551–6787 or *IArules@sec.gov,* Investment Adviser Regulation Office, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Commissions are adopting amendments to Form PF [17 CFR 279.9] under the Advisers Act, and the SEC is adopting amendments to 17 CFR 275.204(b)–1 under the Advisers Act.[1]

[1] 15 U.S.C. 80b. Unless otherwise noted, when we refer to the Advisers Act, or any section of the Advisers Act, we are referring to 15 U.S.C. 80b, at which the Advisers Act is codified, and when we refer to rules under the Advisers Act, or any section of these rules, we are referring to title 17, part 275 of the Code of Federal Regulations [17 CFR 275], in which these rules are published.

[2] Congress enacted Sections 404 and 406 of the Dodd-Frank Act, which required that private fund advisers file reports and specified certain types of information that should be subject to reporting and/or recordkeeping requirements. With respect to such reports, the Dodd-Frank Act authorized the SEC to require that private fund advisers file such information ''as necessary and appropriate in the public interest and for the protection of investors, or for the assessment of systemic risk.'' The result of this enactment was Form PF, which is a joint form between the SEC and CFTC only with respect to sections 1 and 2 of the Form.

Agency	Reference	CFR citation
CFTC & SEC	Form PF [2]	17 CFR 279.9.
SEC	Rule 204(b)–1	17 CFR 275.204(b)–1.

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I. Introduction

The Commissions are adopting amendments to sections of Form PF, the form that certain SEC-registered investment advisers, including those that also are registered with the CFTC as a CPO or CTA, use to report confidential information about the private funds that they advise.[3] Form PF provides the Commissions and FSOC with important information about the basic operations and strategies of private funds and has helped establish a baseline picture of the private fund industry for use in assessing systemic risk. We now have more than a decade of experience analyzing the information collected on Form PF.[4] In that time, the private fund industry has grown in size and evolved in terms of business practices, complexity of fund structures, and investment strategies and exposures.[5] Based on this experience and in light of these changes, the Commissions and FSOC have identified significant information gaps and situations where revised information would improve the Commissions' and FSOC's understanding of the private fund industry and the potential systemic risk posed by it, as well as further investor protection efforts. Accordingly, to enhance FSOC's monitoring and assessment of systemic risk and to collect additional data and make data more useful for the Commissions' use in their respective regulatory programs,[6] in August 2022, the Commissions proposed amendments to enhance the information advisers file on Form PF and improve data quality.[7]

[3] *See* 17 CFR 275.204(b)–1. Advisers Act section 202(a)(29) defines the term ''private fund'' as an issuer that would be an investment company, as defined in section 3 of the Investment Company Act of 1940 (''Investment Company Act''), but for section 3(c)(1) or 3(c)(7) of that Act. Section 3(c)(1) of the Investment Company Act provides an exclusion from the definition of ''investment company'' for any issuer whose outstanding securities (other than short-term paper) are beneficially owned by not more than one hundred persons (or, in the case of a qualifying venture capital fund, 250 persons) and which is not making and does not presently propose to make a public offering of its securities. Section 3(c)(7) of the Investment Company Act provides an exclusion from the definition of ''investment company'' for any issuer, the outstanding securities of which are owned exclusively by persons who, at the time of acquisition of such securities, are qualified purchasers, and which is not making and does not at that time propose to make a public offering of such securities. The term ''qualified purchaser'' is defined in section 2(a)(51) of the Investment Company Act. Any reference to the ''Commissions'' or ''we,'' as it relates to the collection and use of Form PF data, are meant to refer to the agencies in their separate or collective capacities (as the context requires or permits), and such data from filings made pursuant to 17 CFR 275.204(b)–1, by and through Private Fund Reporting Depository, a subsystem of the Investment Adviser Registration Depository (''IARD''), and reports, analysis, and memoranda produced pursuant thereto.

[4] Form PF was adopted in 2011 as required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act''). Public Law 111–203, 124 Stat. 1376 (2010). *See* Reporting by Investment Advisers to Private Funds and Certain Commodity Pool Operators and Commodity Trading Advisors on Form PF, Advisers Act Release No. 3308 (Oct. 31, 2011) [76 FR 71128 (Nov. 16, 2011)], at section I (''2011 Form PF Adopting Release''). In 2014, the SEC amended Form PF section 3 in connection with certain money market fund reforms. *See* Money Market Fund Reform; Amendments to Form PF, Advisers Act Release No. 3879 (July 23, 2014) [79 FR 47736 (Aug. 14, 2014)] (''2014 Form PF Amending Release''). In May 2023, the SEC amended Form PF section 4, added new sections 5 and 6, and redesignated prior section 5 as section 7 in connection with certain amendments to require event reporting for large hedge fund advisers and all private equity fund advisers and to revise certain reporting requirements for large private equity fund advisers. *See* Form PF; Event Reporting for Large Hedge Fund Advisers and Private Equity Fund Advisers; Requirements for Large Private Equity Fund Adviser Reporting, Advisers Act Release No. 6297 (May 3, 2023) [88 FR 38146 (June 12, 2023)] (''May 2023 SEC Form PF Amending Release''). In July 2023, the SEC amended Form PF section 3 in connection with certain money market fund reforms. *See* Money Market Fund Reforms; Form PF Reporting Requirements for Large Liquidity Fund Advisers; Technical Amendments to Form N–CSR and Form N–1A, Advisers Act Release No. 6344 (July 12, 2023) [88 FR 51404 (Aug. 3, 2023)] (''July 2023 SEC Form PF Amending Release''). We are now adopting amendments to the general instructions, section 1, and section 2, and related amendments in the glossary of terms.

[5] The value of private fund net assets reported on Form PF has more than doubled, growing from $5 trillion (net) in 2013 to $14 trillion (net) through the first quarter of 2023, while the number of private funds reported on the form has increased by nearly 130% in that time period. Unless otherwise noted, the private funds statistics used in this Release are from the Private Funds Statistics First Quarter of 2023. Division of Investment Management, Private Fund Statistics First Quarter 2023 (Oct. 16, 2023), *available at https://www.sec.gov/files/investment/private-funds-statistics-2023-q1.pdf* (''Private Fund Statistics Q1 2023''). Any comparisons to earlier periods are from the private funds statistics from that period, all of which are available at *https://www.sec.gov/divisions/investment/private-funds-statistics.shtml.* SEC staff began publishing the private fund statistics in 2015, including data from 2013. Therefore, many comparisons in this Release discuss the ten year span from the beginning of 2013 through the first quarter of 2023. Some discussion in this Release compares data from a shorter time span because the SEC staff published such data later than 2013. Staff reports, statistics, and other staff documents (including those cited herein) represent the views of SEC staff and are not a rule, regulation, or statement of the SEC. The SEC has neither approved nor disapproved the content of these documents and, like all staff statements, they have no legal force or effect, do not alter or amend applicable law, and create no new or additional obligations for any person.

[6] Additionally, the Board of Governors of the Federal Reserve System (''FRB'') uses this data for research and analysis.

[7] Form PF; Reporting Requirements for All Filers and Large Hedge Fund Advisers, Advisers Act Release No. 6083 (Aug. 10, 2022) [87 FR 53832 (Sept. 1, 2022)] (''2022 Joint Form PF Proposing Release''). The Commissions voted to issue the 2022 Joint Form PF Proposing Release on Aug 10, 2022.

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The Commissions received a number of comment letters on the 2022 Joint Form PF Proposing Release.[8] Some commenters generally supported the policy goals of the proposal, stating that the proposal would help the Commissions and FSOC assess and respond to systemic risk and the Commissions to achieve their investor protection goals.[9] Certain commenters stated that the additional proposed reporting requirements are not necessary to identify systemic risk or protect investors.[10] Some commenters stated that the economic analysis understates the costs of compliance due to the scope of proposed changes and expressed skepticism at the stated benefits.[11] Some commenters criticized the proposed rulemaking for not considering the cumulative impact and costs of the amendments proposed in the 2022 Joint Form PF Proposing Release along with those proposed in the 2022 SEC Form PF Proposing Release,[12] which the SEC proposed in January 2022 and adopted in May 2023.[13]

We are adopting the amendments largely as proposed, but with certain modifications, in consideration of the comments we received:

- First, we are adopting amendments to the form's general instructions, which apply to all Form PF filers, to improve data quality and comparability and to enhance investor protection efforts and systemic risk assessment. Amendments include:

○ *Reporting Master-Feeder and Parallel Fund Structures.* As proposed, we are adopting amendments that will require separate reporting for each component fund of a master-feeder arrangement and parallel fund structure, other than a disregarded feeder fund (*i.e.,* a feeder fund that invests all of its assets in a single master fund, U.S. treasury bills, and/or cash and cash equivalents[14]). In a change from the proposal, we are modifying the instructions to specify how a feeder fund is required to treat its equity in the master fund for the purpose of determining its reporting threshold and responding to certain questions.

○ *Reporting Fund of Funds.* We are also adopting, with some modifications from the proposal, amendments to Form PF regarding how advisers report private fund investments in other funds. We are revising proposed Instruction 7 to require an adviser to include the value of investments in other private funds (including internal and external private funds) when determining whether the adviser is required to file Form PF, whether it meets the thresholds for reporting as a large hedge fund adviser, large liquidity fund adviser, or large private equity fund adviser, and whether a hedge fund is a qualifying hedge fund, rather than permit an adviser to either include or exclude the value of investments in other private funds for the purpose of determining its reporting threshold, as proposed.[15]

○ *Reporting Trading Vehicles.* In a change from the proposal, we are adopting an amendment to require advisers to identify trading vehicles in section 1b of Form PF and report on an aggregated basis for the reporting fund and all trading vehicles (whether fully owned by the reporting fund or partially owned), rather than (i) permitting advisers to report fully owned trading vehicles on an aggregated or disaggregated basis and (ii) requiring advisers to report partially owned trading vehicles on a disaggregated basis, as proposed. In a change from the proposal, we are also adding an instruction for advisers to specify whether the reporting fund holds assets, incurs leverage, or conducts trading or other activities through a trading vehicle.

○ *Reporting Timelines.* We are also adopting, as proposed, an amendment to the instructions that will require all quarterly filers to file on a calendar quarter basis, rather than on a fiscal quarter basis.[16]

- Second, we are adopting amendments to sections 1a and 1b of Form PF, which apply to all Form PF filers, to provide greater insight into private funds' operations and strategies, and assist in identifying trends, including those that could create systemic risk and which are as such designed to enhance investor protection efforts and systemic risk assessment. The amendments are also designed to improve comparability across advisers, improve data quality, and reduce reporting errors. We are adopting, as proposed, amendments to collect additional identifying information regarding the adviser and its related persons, as well as their private fund assets under management. We are also adopting, largely as proposed, amendments to require advisers to report additional identifying information about the private funds they manage and other information about the

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The release was posted on each of the Commissions' websites that day (or shortly thereafter), and comment letters were received beginning that same date. The comment period closed on Oct. 11, 2022. We have considered all comments received since Aug. 10, 2022.

[8] The comment letters on the 2022 Joint Form PF Proposing Release (File No. S7–22–22) that the SEC received are available at *https://www.sec.gov/comments/s7-22-22/s72222.htm.* The comment letters that the CFTC received are available at *https://comments.cftc.gov/PublicComments/CommentList.aspx?id=7312.* Several comment letters are addressed jointly to the Commissions and appear in both comment files.

[9] *See, e.g.,* Comment Letter of Americans for Financial Reform Education Fund (Oct. 11, 2022) (''AFREF Comment Letter I''); Comment Letter of Better Markets, Inc. (Oct. 11, 2022) (''Better Markets Comment Letter''); Comment Letter of FACT Coalition (Oct. 11, 2022) (''FACT Coalition Comment Letter''); Comment Letter of Global Legal Entity Identifier Foundation (Oct. 11, 2022) (''GLEIF Comment Letter''); Comment Letter of Americans for Financial Reform Education Fund, et al. (Feb. 21, 2023); Comment Letter of Andrew V. (Aug. 10, 2022).

[10] *See, e.g.,* Comment Letter of American Investment Council (Oct. 11, 2022) (''AIC Comment Letter I''); Comment Letter of U.S. Chamber of Commerce (Oct. 11, 2022) (''USCC Comment Letter''); Comment Letter of Alternative Investment Management Association Limited & Alternative Credit Council (Oct. 11, 2022) (''AIMA/ACC Comment Letter''); Comment Letter of Securities Industry and Financial Markets Association (Oct. 11, 2022) (''SIFMA Comment Letter''); Comment Letter of Managed Funds Association (Dec. 7, 2022) (''MFA Comment Letter II''). *See infra* at sections II and IV.C.1 of this Release for discussion of the benefits of the adopted amendments for systemic risk assessment and investor protection efforts.

[11] *See, e.g.,* AIC Comment Letter I; SIFMA Comment Letter; Comment Letter of Managed Funds Association and National Association of Private Fund Managers (July 21, 2023) (''MFA/NAPFM Comment Letter''). *See* discussion *infra* at section IV.C of this Release.

[12] Amendments to Form PF to Require Current Reporting and Amend Reporting Requirements for Large Private Equity Advisers and Large Liquidity Fund Advisers, Advisers Act Release No. 5950 (Jan. 26, 2022) [87 FR 9106 (Feb. 17, 2022)] (''2022 SEC Form PF Proposing Release'').

[13] *See, e.g.,* AIC Comment Letter I; Comment Letter of Managed Funds Association, Investment Adviser Association, et al. (Sept. 14, 2022) (''MFA Comment Letter I''); Comment Letter of Managed Funds Association (Mar. 16, 2023) (''MFA Comment Letter III''); SIFMA Comment Letter; Comment Letter of United States House of Representatives Committee on Financial Services (Sept. 26, 2023) (''Comment Letter of U.S. House of Representatives Committee on Financial Services''). *See also* May 2023 SEC Form PF Amending Release, *supra* footnote 4. *See also* Comment Letter of AIC (Aug. 8, 2023) (''AIC Comment Letter II''). See *infra* section IV.C of this Release for discussion of costs and benefits.

[14] As discussed in greater detail below, we are removing government securities from the definition of ''cash and cash equivalents'' and presenting government securities as its own line item in the Form PF Glossary of Terms. Thus, references herein to ''cash and cash equivalents'' refer to the amended definition, unless otherwise indicated. The amended definition is intended to provide more granular detail on this reporting form and is not intended to change any commercial understanding or accounting treatment of cash equivalents. *See infra* section II.B.2 of this Release.

[15] *See* Instruction 7.

[16] The calendar quarter basis filing requirement does not apply to a private equity fund adviser filing a private equity event report as contemplated by section 6 of Form PF, which requires such adviser to file within 60 calendar days after the end of the applicable fiscal quarter upon the occurrence of a private equity reporting event. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4.

private funds' assets, financing, investor concentration, and performance.

- Third, we are adopting amendments to section 1c of Form PF, which applies to private fund advisers that advise hedge funds. We are adopting, largely as proposed, amendments to require advisers to hedge funds to report certain additional information. As proposed, we are adopting amendments to require advisers to hedge funds to report on the fund's use of digital assets as an investment strategy, but in a modification from the proposal, we are not adopting the proposed definition of digital assets. We are also adopting, as proposed, amendments to remove certain questions to streamline reporting and to reduce reporting burdens.
- Fourth, as proposed, we are redesignating existing section 2a and 2b of Form PF as section 2, and we are adopting amendments to the new consolidated section 2, which applies to large hedge fund advisers that advise qualifying hedge funds (*i.e.,* hedge funds that have a net asset value of at least $500 million). As proposed, we are removing aggregate reporting questions for large hedge fund advisers and requiring additional fund-level reporting to enhance investor protection efforts and systemic risk assessment.[17] We are adopting, largely as proposed, amendments to require large hedge fund advisers to report more granular information about the reporting fund's investment exposure, open and large position reporting, borrowing and counterparty exposure, and market factor effects. In a change from the proposal, we are not adopting a proposed question about investment performance by portfolio correlation.
- Finally, we are adopting, largely as proposed, certain additional amendments to improve data quality and accuracy of reporting.

The amendments we are adopting are important enhancements to the ability to monitor and assess systemic risk and to determine whether and how to deploy the Commissions' or FSOC's regulatory tools. The amendments will also strengthen the effectiveness of the SEC's regulatory programs, including examinations, investigations, and investor protection efforts relating to private fund advisers. The Commissions consulted with FSOC to gain input on these amendments and to help ensure that Form PF continues to provide FSOC with information it can use to assess systemic risk.

[17] Unless stated otherwise, terms in this release that are defined in the Form PF Glossary of Terms are as defined therein.

II. Discussion

A. Amendments to the General Instructions

We are adopting amendments to the Form PF general instructions designed to improve data quality and comparability and to enhance investor protection efforts and systemic risk assessment.[18]

1. Reporting Master-Feeder Arrangements and Parallel Fund Structures

Private funds often use complex structures to invest, including master-feeder arrangements and parallel fund structures.[19] We are adopting, largely as proposed, amendments to Form PF that generally require advisers to report separately each component fund of a master-feeder arrangement and parallel fund structure.[20] An adviser will continue to aggregate these structures, however, for purposes of determining whether the adviser meets a reporting threshold.[21]

Currently, Form PF provides advisers with flexibility to respond to questions regarding master-feeder arrangements and parallel fund structures either in the aggregate or separately, as long as they do so consistently throughout Form PF.[22] In adopting this approach in 2011, the Commissions stated that requiring advisers to aggregate or disaggregate funds in a manner inconsistent with their internal recordkeeping and reporting may impose additional burdens and that, as long as the structure of those arrangements is adequately disclosed, a prescriptive approach to aggregation was not necessary.[23] However, based on experience reviewing Form PF data, we observed that when some advisers report in aggregate and some advisers report separately, this can result in obscured risk profiles (*e.g.,* with respect to asset size, counterparty exposure, investor liquidity) and make it difficult to compare complex structures, undermining the utility of the data collected.[24] Prescribing the way advisers report a master-feeder arrangement and parallel fund structure will provide better insight into the risks and exposures of these arrangements.

Accordingly, we are amending the instructions to require an adviser to report each component fund of a master-feeder arrangement and parallel fund structure, except where a feeder fund invests all its assets in a single master fund, U.S. treasury bills, and/or ''cash and cash equivalents'' (*i.e.,* is a disregarded feeder fund).[25] In the case

[18] Additional adopted changes to the General Instructions concerning amendments to enhance data quality methodologies and additional amendments are discussed in sections II.D and II.E of this Release. The amendments to Instruction 3 to reflect the removal of section 2a are discussed in section II.C.1 of this Release.

[19] A ''master-feeder arrangement'' is an arrangement in which one or more funds (''feeder funds'') invest all or substantially all of their assets in a single private fund (''master fund''). A ''parallel fund structure'' is a structure in which one or more private funds (each, a ''parallel fund'') pursues substantially the same investment objective and strategy and invests side by side in substantially the same positions as another private fund. *See* Form PF Glossary of Terms.

[20] *See* Instruction 6. We also are amending Instruction 3, as proposed, to reflect the adopted approach for reporting master-feeder arrangements and parallel fund structures. *See infra* footnote 21.

[21] *See* Instruction 5. For example, an adviser would aggregate private funds that are part of the same master-feeder arrangement in determining whether the adviser is a large hedge fund adviser that must complete section 2 of Form PF. In connection with these changes, we are amending, as proposed, the term ''reporting fund'' and Instruction 3 so that they no longer discuss reporting aggregated information. Additionally, we are reorganizing current Instruction 5 and current Instruction 6 so that they reflect the adopted approach for when to aggregate certain funds. Current Instruction 5 instructs advisers about when to aggregate information about certain funds for purposes of reporting thresholds and responding to questions. Current Instruction 6 instructs advisers about how to aggregate information about certain funds. Instruction 5, as amended, instructs advisers on when to aggregate information about certain funds for purposes of determining whether they meet reporting thresholds. Instruction 6, as amended, instructs advisers about how to report information about certain funds when responding to questions. Further, in a modification from the proposal, we have added a reference to section 5 (Current report for large hedge fund advisers to qualifying hedge funds), which a qualifying hedge fund would also be required to complete, as applicable, as a result of the amendments adopted in the May 2023 SEC Form PF Amending Release.

[22] *See* current Instruction 5.

[23] 2011 Form PF Adopting Release, *supra* footnote 4, at text following n.332.

[24] For example, a feeder fund may have counterparty exposure rather than the entire fund in the aggregate. When this is the case, fewer assets (*e.g.,* only those held at the feeder level) may be available as collateral and the counterparty may have greater risk.

[25] *See* Instruction 6. We are also revising the term ''cash and cash equivalents,'' as described in section II.B.2 in this Release, to improve data quality and provide more granular detail of fund exposures to the Commissions and FSOC. In alignment with this revision, we have modified the term ''disregarded feeder fund'' for the purposes of Form PF to specifically include U.S. treasury bills. U.S. treasury bills are direct obligations of the U.S. Government with a maturity of one year or less. Because these short-term holdings are sufficiently cash-like for our reporting and data analysis purposes, separate reporting for a feeder fund that invests all of its assets in U.S. treasury bills (or some combination of U.S. treasury bills, ''cash and cash equivalents,'' and a single master fund) is not necessary. One commenter stated that the removal of government securities from the definition of cash and cash equivalents would reduce the number of funds that qualify as disregarded feeder funds. *See* AIMA/ACC Comment Letter. This commenter stated that the Commission should revise the definition to allow for disregarded feeder funds to invest in government securities. *Id.* The final

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of a disregarded feeder fund in Question 6, advisers instead will identify the disregarded feeder fund and look through to any disregarded feeder fund's investors in responding to certain questions regarding fund investors on behalf of the applicable master fund, as proposed. The master fund effectively is a conduit through which a disregarded feeder fund invests, and we do not believe separate reporting for such a feeder fund is necessary for data analysis purposes. In a modification from the proposal, we are adopting instructions to specify that a feeder fund should disregard any of its holdings in the master fund's equity for the purpose of determining its reporting threshold.[26]

Some commenters generally supported the proposed amendments that require more granular reporting of private fund structures because this would allow FSOC to assess systemic risk and the Commissions to protect investors more effectively.[27] Other commenters generally opposed the proposed amendments to require disaggregated reporting of master-feeder funds and parallel fund structures, stating that it would be overly burdensome for advisers to report this information and of limited benefit to the Commissions and/or FSOC.[28]

Although we acknowledge that the requirement to report disaggregated data for parallel fund and master-feeder fund structures may increase the reporting burdens on certain advisers, we disagree that requiring disaggregated reporting would be significantly more burdensome than the existing requirements, because filers are already required to assemble aggregated data from the individual components of their fund structures to determine their reporting category on Form PF.[29] Any increased burdens are justified because disaggregated data of these structures will provide the Commissions and FSOC with increased transparency into risk profiles and complex fund structures, which will improve our ability to monitor systemic risk and protect investors. We also disagree that disaggregated reporting of master-feeder funds and parallel fund structures will be of limited value based on our experience with Form PF, which currently obscures our understanding of their fund structures and the risk exposure of their component funds. Some commenters opposed the proposed disaggregated reporting requirement, asserting that it would provide misleading information by reporting data in isolation as opposed to as part of an overall fund or investment program.[30] However, rather than be misleading, the disaggregated reporting will allow for a clearer understanding of a fund's structure. Disaggregated data will not be misleading to the Commissions or FSOC in comparison to aggregated data because the disaggregated data can still be aggregated by FSOC and the Commissions if necessary to understand and assess the risk of the fund.

One commenter stated that the disaggregated reporting requirement would be particularly burdensome for private equity fund advisers, as this commenter believed private equity funds pose less systemic risk.[31] The existing reporting instructions allowing aggregated reporting result in an obscured risk profile of all types of private funds, including private equity funds. Although private equity funds may exhibit a different risk profile than hedge funds, we disagree with the commenter that understanding their structure is unimportant to assessing systemic risk. Understanding the full risk profile of private equity funds is an important component of the reporting on Form PF because of the growth in the private equity fund industry and its significance to financial markets.[32] Additionally, the disaggregated reporting requirement is important for investor protection efforts due to the increased exposure of investors to the private equity industry through investments such as pension funds.[33]

One commenter stated that requiring disaggregated data would add a data security risk that sensitive information about a fund's strategy could be publicly exposed.[34] We do not agree that requiring disaggregated reporting of component funds presents a significant increase in public disclosure risk, in part because the required information is no more granular than the information already required to be reported for other private funds without a master-feeder arrangement or parallel fund structure. The Commissions currently have robust data protection measures in place to protect all information filed on Form PF, which is filed on a non-public basis. Any limited increase in data security risk associated solely with the collection of more information is justified because of the importance of receiving this disaggregated information for FSOC and the Commissions' systemic risk monitoring and the Commissions' investor protection efforts. As discussed more fully above, this disaggregated data will provide increased transparency into complex fund structures and better insight into the risks presented by such arrangements. As discussed above, in response to commenters' concerns, we are modifying the instructions for how a feeder fund determines its reporting category to specify that the feeder fund should exclude any of its holdings in the master fund's equity when calculating its total asset value for the purpose of determining its reporting category.[35] This modification will help avoid double counting of reported assets, given that data for the master fund will be separately reported on Form PF. It will also require a more appropriate level of information from feeder funds than we had proposed. As proposed, an adviser could have determined that a feeder fund is a qualifying hedge fund subject to additional reporting, even if the feeder fund's investments outside of its master fund were trivial. This level of reporting for such a feeder fund is not necessary for data analysis purposes, and the amended Form PF will accordingly only require this additional reporting for feeder funds that are determined to be qualifying hedge funds based on their investments made outside of their master funds. Some commenters recommended adopting an instruction for disregarded feeder fund reporting obligations that allows for a *de minimis* amount of a disregarded feeder fund's investments to be in other assets, such as up to 10 or 20 percent of a fund's capital, rather than the proposed instruction, which would require all of the disregarded feeder fund's assets to be invested in a single master fund, U.S. treasury bills, or cash and cash

amendments permit disregarded feeder funds to invest in U.S. treasury bills, but not other government securities. We believe this approach is appropriate because, as noted above and unlike certain other government securities, U.S. treasury bills are short-term holdings and sufficiently cash-like for our reporting and data analysis purposes. Further, U.S. treasury bills generally do not have the interest rate risk that longer-dated government securities have.

[26] *See* Instruction 6.

[27] *See, e.g.,* AFREF Comment Letter I; Better Markets Comment Letter.

[28] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II.

[29] *See* current Instruction 5.

[30] *See, e.g.,* MFA Comment Letter II; USCC Comment Letter.

[31] AIC Comment Letter I.

[32] Since 2013, the number of private equity funds has more than doubled from under 7,000 to over 20,000, private equity fund gross assets have quadrupled from $1.6 trillion to $6.6 trillion, and private equity fund net assets have also quadrupled, increasing from $1.5 trillion to $6 trillion. *See* Private Fund Statistics Q1 2023, *supra* footnote 4.

[33] *See, e.g.,* Public Plans Data (2022), *available at https://publicplansdata.org/quick-facts/national/.*

[34] USCC Comment Letter.

[35] *See* Instruction 6.

equivalents.[36] We do not believe that these recommended exceptions would be appropriate. The adopted instruction, which provides that a feeder fund that invests all of its assets in a single master fund, U.S. treasury bills, or cash and cash equivalents is a disregarded feeder fund, is more appropriate because such a feeder fund is effectively investing only through its associated master fund. Disaggregated reporting of such a disregarded feeder fund is not necessary for data analysis purposes, because such reporting would not convey additional information about the feeder fund's exposures, as the feeder fund's investments are limited to its investments through its master fund, which are required to be reported on the amended Form PF. In contrast, a feeder fund that does not invest all of its assets in a single master fund, U.S. treasury bills, or cash and cash equivalents operates and invests in a different manner, and it is critical to our understanding of these funds and the risks that they may pose to receive disaggregated reporting of these fund arrangements because such feeder funds will generally have distinct risk exposures than their associated master funds. Further, the modified instructions we are adopting, which provide that a reporting feeder fund is to disregard its holdings in the master fund's equity for the purpose of determining its reporting threshold, are responsive to commenter concerns that the burdens on feeder funds with *de minimis* non-cash or cash equivalent holdings would be significant. For example, under the adopted instructions, a feeder fund with minimal holdings outside of the master fund's equity may only be required to complete section 1 of Form PF, when it may have otherwise been required to complete additional sections if its holdings in the equity of the master fund were included in its reporting threshold determination, as proposed. The modified instructions take into consideration the potential burden of reporting feeder funds on a separate basis and allows the Commissions to receive important reporting on the exposures of feeder funds other than to its equity in its master fund.

In addition, we are adopting, as proposed, an amendment to no longer allow advisers to separately report any ''parallel managed accounts'' (which is distinguished from a ''parallel fund structure''), provided that advisers will continue to be required to report the total value of all parallel managed accounts related to each reporting fund.[37] Including parallel managed accounts in the reporting may reduce the quality of data for our analyses while also imposing additional burdens on advisers.[38] Data regarding the total value of parallel managed accounts, however, will allow FSOC to take into account the greater amount of assets an adviser may be managing using a given strategy for purposes of analyzing the data reported on Form PF for systemic risk purposes.

We are adopting, as proposed, an instruction to provide that a dependent parallel managed account must be aggregated with the largest private fund to which it relates and, unchanged from the current Form PF, with respect to any private fund, a ''dependent parallel managed account'' remains defined as any related parallel managed account other than a parallel managed account that individually (or together with other parallel managed accounts that pursue substantially the same investment objective and strategy and invest side by side in substantially the same positions) has a gross asset value greater than the gross asset value of such private fund (or, if the private fund is a parallel fund, the gross asset value of the parallel fund structure).[39] One commenter sought clarification that a parallel managed account should be aggregated with the single largest private fund to which it relates.[40] We continue to believe that this approach will more effectively support systemic risk analyses and our investor protection efforts, particularly given the growth in parallel managed accounts in recent years.[41]

2. Reporting Private Funds That Invest in Other Funds

We are adopting amendments to Form PF regarding how advisers report private fund investments in other private funds, trading vehicles, and other funds that are not private funds.

Investments in other private funds. We are adopting, with modifications from the proposal, amendments to Instruction 7, which addresses how advisers treat private fund investments in other private funds (*e.g.,* a ''fund of funds''). Currently, advisers include the value of private fund investments in other private funds in determining whether the adviser meets the filing threshold to file Form PF.[42] This requirement is implicit in the current form, and we are amending this aspect of Instruction 7, as proposed, to make it explicit. Further, current Form PF generally permits an adviser to disregard the value of a private fund's equity investments in other private funds for purposes of both the form's reporting thresholds (*e.g.,* whether it qualifies as a large hedge fund adviser) and responding to questions on Form PF, as long as the adviser does so consistently throughout Form PF, subject to certain exceptions.[43] We proposed continuing to permit an adviser to either include or exclude the value of such investments for the purpose of determining its reporting thresholds but requiring an adviser to include the value of such investments for the purpose of responding to questions on Form PF.

In a modification from the proposal, we are adopting an amendment to Instruction 7 to require an adviser to include the value of investments in other private funds (including internal and external private funds) when determining whether the adviser is required to file Form PF, whether it meets the thresholds for reporting as a large hedge fund adviser, large liquidity fund adviser, or large private equity fund adviser, and whether a hedge fund is a qualifying hedge fund, rather than permit an adviser to either include or exclude the value of investments in other private funds for the purpose of determining its reporting threshold, as

[36] *See* AIMA/ACC Comment Letter; MFA Comment Letter II.

[37] *See* Instruction 6. A ''parallel managed account'' is any managed account or other pool of assets managed by the adviser that pursues substantially the same investment objective and strategy and invests side by side in substantially the same positions as the identified private fund. *See* Form PF Glossary of Terms.

[38] *See* 2011 Form PF Adopting Release, *supra* footnote 4, at n.334, and accompanying text (the Commissions were persuaded that aggregating parallel managed accounts for reporting purposes would be difficult and ''result in inconsistent and misleading data'' because the characteristics of parallel managed accounts are often somewhat different from the funds with which they are managed). For example, in a separately managed account a client generally selects an adviser's strategy but tailors it to the client's own investment guidelines.

[39] *See* Instruction 5; Form PF Glossary of Terms.

[40] AIMA/ACC Comment Letter.

[41] *See* David C. Johnson & Francis A. Martinez, *Form PF Insights on Private Equity Funds and Their Portfolio Companies,* Office of Financial Research, June 14, 2018, at 3–4, *available at https://www.financialresearch.gov/briefs/files/OFRBr_2018_01_Form-PF.pdf* (stating that fund investments in other funds increased from $227 billion in 2013 to $319 billion in 2016 and noting that the existing reporting on parallel managed accounts may be underreported because parallel managed accounts are not currently required to be reported).

[42] Form PF Instruction 1 provides that certain advisers meet the filing threshold if they and their related persons, collectively, had at least $150 million in private fund assets under management as of the last day of their most recently completed fiscal year.

[43] For example, under the current instructions, an adviser is not permitted to disregard any liabilities of the private fund, even if incurred in connection with an investment in other private funds. *See* current Instruction 7.

proposed.[44] As discussed further below, as proposed, an adviser will no longer have flexibility on whether to include or exclude a reporting fund's investments in other private funds for purposes of responding to questions on Form PF.[45] Instead, we are amending Instruction 7 to require an adviser to include the value of a reporting fund's investments in other private funds when responding to questions on Form PF, unless otherwise directed by the instructions to a particular question.

Requiring advisers to report fund of funds arrangements in a more consistent manner will allow the Commissions and FSOC to understand these fund structures more effectively by providing greater insight into the scale of reporting funds' exposures. The form's current flexibility on whether to disregard underlying funds for the purpose of determining a reporting fund's reporting threshold and when responding to questions provides unclear and inconsistent reporting and data on the scale of reporting funds' exposures.

One commenter stated that allowing an adviser to determine whether to include or exclude a reporting fund's investment in other private funds could result in distortions in the data collected on Form PF.[46] This commenter recommended revising the instructions to prohibit an adviser from including a reporting fund's investment in other private funds for the purpose of determining its reporting threshold. We agree with this commenter that permitting advisers the flexibility to include or exclude the value of the reporting fund's investment in other private funds could result in distortions in the data and inconsistent reporting. Therefore, we have modified the instructions to remove this proposed flexibility. However, we have modified the instructions to provide that an adviser must include the reporting fund's investment in other private funds for determining its reporting threshold. For the same reasons that Instruction 7 currently (and will continue to) provide that an adviser must include the reporting fund's investments in other private funds in determining whether it is required to file Form PF, we believe it is appropriate for an adviser to use this same approach to determine the reporting fund's appropriate reporting category. This modification will provide for consistent treatment of investments in other private funds for all Form PF purposes by specifying that these investments should be included for the purpose of determining reporting threshold, determining filing threshold, and responding to questions on Form PF (unless otherwise instructed by a particular question). We do not believe that this modification will materially increase filing burdens because advisers are currently (and will continue to be) required to include the value of the reporting fund's investments in other private funds for the purpose of determining whether it is required to file Form PF and, as discussed further below, will be required, as proposed, to include the value of the reporting fund's investments in other private funds in answering questions on Form PF (unless otherwise instructed by a particular question). Some commenters opposed the proposed amendment to include the value of a reporting fund's investment in other external private funds when responding to questions because of the burden of obtaining information about the underlying investments and their view on the limited value of the data.[47] Data about underlying investments in external private funds is important to provide the Commissions and FSOC with sufficient information to understand a fund structure to be able to assess systemic risk. We disagree that reporting the value of a reporting fund's investments in other external private funds is significantly more burdensome to report because an adviser is currently required to calculate the value of its investment in other private funds in determining whether the adviser meets the threshold to file Form PF. One commenter stated that investments in private funds should be treated like a disregarded feeder fund and not require disaggregated reporting.[48] We disagree that a fund of funds structure presents the same risks as a disregarded feeder fund because, in a fund of funds structure, the feeder fund is itself engaging in direct investment, whereas a disregarded feeder fund invests its assets at the master fund level.

Currently, Instruction 7 specifies that, in the case of a fund that invests substantially all of its assets in other private funds and, other than its investments in other private funds, only holds cash and cash equivalents and instruments acquired for the purpose of hedging currency exposure, an adviser is only required to complete section 1b of Form PF for that fund.[49] One commenter recommended modifying this instruction to replace the reference to ''substantially all of its assets'' in other private funds to 80% of its assets and to remove the reference to only holding cash and cash equivalents and instruments acquired for the purpose of hedging currency exposure.[50] This commenter stated that there are circumstances that may cause an adviser to invest a small portion of a fund of fund's assets directly, such as for tax purposes or for an investor's preference, which would cause the fund to no longer be considered a fund that invests substantially all of its assets in other private funds for purposes of Form PF, which allows the adviser to only complete section 1b for that fund.[51] Although we agree that the meaning of ''substantially all of its assets'' should be clarified for purposes of this form, so as to generally improve data quality and comparability, we disagree that the reference to only holding cash and cash equivalents and instruments acquired for the purpose of hedging currency exposure should be removed. The exclusion from completing section 1c is intended to be limited to funds that invest only through other private funds for which we receive separate reporting. Allowing an exclusion for funds that invest in investments other than private funds would create a data gap because we would not receive separate reporting about investments that are *not* private funds. Accordingly, in a change from the proposal, we are modifying Instruction 7 only to replace the instruction ''substantially all of its assets'' to ''80% or more of its assets.'' This modification will help clarify which funds will need to complete only section 1b of Form PF.

Currently, advisers are not required to, but nonetheless have the option to, ''look through'' a reporting fund's investments in any other entity (including other private funds), except in instances when the form directs otherwise.[52] As a result, some advisers may ''look through'' a reporting fund's investments in other entities, while others do not, leading to unclear data, inconsistent comparisons, and less precise analysis across advisers. Therefore, we are amending, largely as proposed, Instruction 7 to provide that, when responding to questions, advisers must not ''look through'' a reporting fund's investments in internal private

[44] *See* Instruction 7. In connection with this Instruction 7, we are also not adopting the proposed revision to the definition of ''qualifying hedge fund,'' which would have instructed advisers that they may exclude the fund's investments in other private funds in determining whether a hedge fund meets the ''qualifying hedge fund'' definition. *See* Form PF Glossary of Terms.

[45] *Id.*

[46] AIMA/ACC Comment Letter.

[47] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II.

[48] AIMA/ACC Comment Letter.

[49] *See* current Instruction 7.

[50] AIMA/ACC Comment Letter.

[51] *Id.*

[52] *See* current Instruction 8.

funds or external private funds (other than a trading vehicle, as described below), unless the question instructs the adviser to report exposure obtained indirectly through positions in such funds or other entities.[53] In a modification from the proposal, we are adding an instruction that provides if an adviser cannot avoid ''looking through'' to the reporting fund's investments in internal private funds or external private funds in responding to a particular question, then the adviser must provide an explanation of its responses in Question 4. This instruction is responsive to certain commenters' concerns regarding the burden of disaggregated reporting where look-through aggregation may be unavoidable and will provide additional context for the data reported. Further, after consideration of commenter recommendations, in a modification from the proposal, we are revising certain questions related to exposures to instruct advisers to select the exposure that ''best represents'' the indirect investment of the reporting fund, as discussed more fully below in section II.C.[54] This modification will reduce the burden on advisers in reporting exposure information about these investments in private funds, while providing reporting on indirect investments that is important for effective systemic risk assessment and investor protection efforts.

As discussed further below, we are modifying from the proposal the reporting instructions for trading vehicles to require an adviser to ''look through'' trading vehicles for all questions. Given this modification, we are also adopting amendments to Instruction 8 to exclude trading vehicles from the general requirement that an adviser must not ''look through'' a reporting fund's investments in funds or other entities unless the question instructs the adviser to report exposure obtained indirectly through positions in such funds or other entities. These amendments are designed to improve data quality and comparisons, so the Commissions and FSOC understand what Form PF data is from advisers ''looking through'' a reporting fund's investments, which will lead to more effective systemic risk assessments and investor protection efforts.

Trading vehicles. Some private funds wholly or partially own separate legal entities that hold assets, incur leverage, or conduct trading or other activities as part of the private fund's investment activities, but do not operate a business (each, a ''trading vehicle'').[55] Private funds may use trading vehicles for various purposes, including (1) for jurisdictional, tax, or other regulatory purposes or (2) to ''ring-fence'' assets in light of liability or bankruptcy concerns associated with a particular investment (*i.e.,* structure assets so counterparties would only have recourse against the trading vehicle and not against the private fund). Currently, Form PF does not require advisers to identify trading vehicles. As a result, Form PF does not provide a clear window into the existence or use of trading vehicles and the risks that they present. Because private funds may use trading vehicles for a wide variety of purposes, more complete and accurate visibility into asset class exposures, position sizes, and counterparty exposures relied on by trading vehicles can enhance the Commissions' and FSOC's systemic risk and financial stability assessment efforts and the Commissions' efforts to protect investors by identifying areas in need of outreach, examination, or investigation. We are adopting amendments designed to address these concerns by requiring advisers to identify any trading vehicles of the reporting fund, how the reporting fund uses the trading vehicle, and the position sizes and counterparty exposures of the reporting fund that are attributable to the trading vehicle.

We are adopting amendments, with certain modifications from the proposal, to Form PF's general instructions to explain how advisers report information if the reporting fund uses a trading vehicle.[56] Specifically, if the reporting fund uses a trading vehicle, the adviser will be required to identify the trading vehicle in section 1b and report answers on an aggregated basis for the reporting fund and such trading vehicle.[57] Advisers will be instructed to ''look through'' the trading vehicle's holdings on Form PF, adjusted for the reporting fund's percentage ownership interest of the trading vehicle, in responding to questions on Form PF for the reporting fund, as discussed further below.[58] As discussed more fully in section II.B below, an adviser will also be required to specify if the reporting fund holds assets through a trading vehicle, incurs leverage through a trading vehicle, or conducts trading or other activities through a trading vehicle.[59] Finally, advisers will be required to report trading vehicles on a consolidated basis but in response to certain questions will be required to identify the positions and counterparty exposures that are held through a trading vehicle, which will help differentiate the reporting fund's exposures and risks from those of its trading vehicles, as discussed more fully in sections II.B.3 and II.C.2 below.[60]

[53] *See* Instruction 7. For example, advisers will not ''look through'' to the creditors of or counterparties to other private funds in responding to questions that ask about a reporting fund's borrowings and counterparty exposures. *See* Question 18 (concerning borrowings) and Questions 27 and 28 (concerning counterparty exposures). However, selected questions in section 2 of the form require advisers to report indirect exposure resulting from positions held through other entities including private funds, and advisers will ''look through'' the reporting fund's investments in internal private funds and external private funds in responding to those questions. *See, e.g.,* Question 32 (concerning reporting fund exposures).

[54] *See* Questions 33, 35, 36, and 47.

[55] We are adopting a definition of ''trading vehicle'' to the Form PF Glossary of Terms. In a modification from the proposed definition, we are specifying that a trading vehicle may be wholly *or partially* owned by a reporting fund. *See* Form PF Glossary of Terms (definition of ''trading vehicle''). The concept of a partially owned trading vehicle (*i.e.,* if the reporting fund is not the trading vehicle's only equity owner) was implicit in the proposed instructions, which would have provided for different treatment for a wholly owned or partially owned trading vehicle. *See* proposed Instruction 7. We are modifying the definition of ''trading vehicle'' to make this explicit.

[56] *See* Instruction 7. We are also making a conforming change to Instruction 8 to reference this new instruction.

[57] We proposed the following for reporting requirements for trading vehicles: if the reporting fund uses a trading vehicle, and the reporting fund is its only equity owner, the adviser would have been required to either (1) identify the trading vehicle in section 1b and report answers on an aggregated basis for the reporting fund and such trading vehicle, or (2) report the trading vehicle as a separate reporting fund. An adviser would have been required to report the trading vehicle separately if the trading vehicle holds assets, incurs leverage, or conducts trading or other activities on behalf of more than one reporting fund. If reporting separately, (1) advisers would have been required to report the trading vehicle as a hedge fund if a hedge fund invests through the trading vehicle; (2) advisers would have been required to report the trading vehicle as a qualifying hedge fund if a qualifying hedge fund invests through the trading vehicle; or (3) otherwise, advisers would have been required to report the trading vehicle as a liquidity fund, private equity fund, or other type of fund based on its activities.

[58] *See* Instruction 7. We had proposed to permit disaggregated reporting for wholly-owned trading vehicles and to require disaggregated reporting for partially-owned trading vehicles. As discussed below, the final amendments will instead require advisers to report all trading vehicles, whether wholly or partially owned, on a consolidated basis. In connection with this change, the final amendments specify that an adviser must adjust trading vehicle information to reflect the reporting fund's percentage ownership interest of the trading vehicle.

[59] *See* Questions 9(d) through (f). A trading vehicle is defined as a separate legal entity, wholly or partially owned by one or more reporting funds, that holds assets, incurs leverage, or conducts trading or other activities as part of a reporting fund's investment activities but does not operate a business. *See* Form PF Glossary of Terms (definition of ''trading vehicle''). Questions 9(d) through (f) ask the reporting fund to identify the vehicle's activities that results in it being a ''trading vehicle,'' as defined in the Form PF Glossary of Terms.

[60] *See, e.g.,* Questions 27 and 28, which are required for all hedge fund advisers, and Questions

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We are not adopting proposed amendments that would have permitted an adviser to select whether to report a wholly owned trading vehicle on either a consolidated or disaggregated basis and would have required advisers to report a partially owned trading vehicle on a disaggregated basis. One commenter stated the proposed disaggregated reporting for trading vehicles would provide the Commissions and FSOC with insights into a private fund's assets and activities that are not currently reported on Form PF, which would support assessment of potential systemic risk.[61] Other commenters opposed the proposed requirements to disclose trading vehicles on a disaggregated basis because of the significant cost and burdens for such reporting and their view on the limited benefit of such reporting to the Commissions.[62] Some commenters stated that disaggregated reporting of trading vehicles would be misleading because advisers do not account for risk on a disaggregated basis.[63] Another commenter stated that allowing consolidated reporting of trading vehicles would provide the Commissions with a clearer and more accurate depiction of a fund's characteristics and exposures than disaggregated reporting.[64] Some commenters stated that separate reporting for trading vehicles is not necessary because trading vehicles are often used for administrative purposes, such as for tax or efficiency purposes, but are managed on a consolidated basis and regarded as a single entity for investment purposes.[65] Another commenter recommended limiting disaggregated reporting of trading vehicles to only vehicles that engage in leverage or borrowing to reduce the cost of implementation of separate reporting.[66] Another commenter recommended that we focus on specific questions on Form PF to gain information about trading vehicles instead of requiring full separate reporting of trading vehicles to reduce burdens and provide clearer reporting.[67] Another commenter recommended permitting aggregated reporting for trading vehicles that are at least 90% owned by a single reporting fund.[68]

After considering such comments, we are not adopting the proposed requirement that would have permitted advisers to report fully owned trading vehicles on a disaggregated basis and required them to do so in the case of partially owned trading vehicles. Instead, we are requiring advisers to report all trading vehicles, whether wholly owned or partially owned, on a consolidated basis. Requiring advisers to instead ''look through'' the reporting fund's investment in all trading vehicles on a consistent basis is appropriate because receiving disaggregated data for some but not all trading vehicles could result in distorted data. Requiring all reporting funds to report their trading vehicles, whether fully or partially owned, on an aggregated basis will improve data comparability and allow us to better understand the holdings and exposures of the fund structure for our assessments of potential systemic risk. We also understand from commenters that a consolidated reporting better aligns with how advisers regard trading vehicles internally. However, after considering a commenter's recommendation to include specific questions on trading vehicles rather than full disaggregated reporting,[69] we are adopting amendments to include specific questions relating to a reporting fund's trading vehicle use and a trading vehicle's position size and risk exposure, as opposed to requiring the greater burden of full separate reporting on Form PF for trading vehicles. We are also requiring advisers to identify the relevant party that bears certain risk exposures, which will allow us to understand how the reporting fund makes use of its fund structure, including any trading vehicles.[70] This approach will result in greater insight into the overall fund structure and support of FSOC's systemic risk assessments than under the existing reporting requirements, and it will also be less burdensome than the approach we had proposed to require separate full reporting for certain trading vehicles. We disagree that any trading vehicle reporting should be limited to only vehicles that are used for leverage and borrowing activities because the amendments are intended to support systemic risk assessments more broadly on and provide insight into how trading vehicles are used, which includes trading vehicles that are used for other purposes, such as holding assets or trading. This reporting is important for systemic risk assessment because it provides visibility into private funds' operations and can assist the Commissions and FSOC in identifying trends across the industry.

Investments in funds that are not private funds. Advisers will continue to include the value of the reporting fund's investments in funds and other entities that are not private funds, in determining reporting thresholds and responding to questions, unless otherwise directed, as Form PF currently requires.[71] For the reasons discussed above, we are revising the instructions, substantially as proposed, to indicate that, when responding to questions, however, advisers must not ''look through'' a reporting fund's investments in funds or other entities that are not private funds, or trading vehicles, unless the question instructs the adviser to report exposure obtained indirectly through positions in such funds or other entities.[72]

3. Reporting Timelines

We are amending, as proposed, Instruction 9 to require large hedge fund advisers and large liquidity fund advisers to update Form PF within a certain number of days after the end of each calendar quarter, rather than after each fiscal quarter, as Form PF currently requires.[73] One commenter stated that for quarterly filers who have a fiscal year ending in a non-calendar quarter month, the proposed instructions do not specify the procedure for a filer who, during the transition from fiscal to calendar quarter reporting, would otherwise be required to report twice in one calendar quarter.[74] As suggested by this commenter, we are requiring that such filers transition to the new timing requirement by their first calendar quarter-end filing for the first full quarterly reporting period after the compliance date.[75]

42, 43, and 44, which are required for large hedge fund advisers.

[61] NASAA Comment Letter.

[62] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter.

[63] *See, e.g.,* MFA Comment Letter II; MFA/NAPFM Comment Letter.

[64] AIMA/ACC Comment Letter.

[65] *See, e.g.,* MFA Comment Letter II; Schulte Comment Letter.

[66] SIFMA Comment Letter.

[67] Schulte Comment Letter.

[68] MFA Comment Letter II.

[69] Schulte Comment Letter.

[70] *See, e.g.,* Questions 27 and 28, which are applicable to all hedge funds, and Questions 42, 43, and 44, which are applicable to only large hedge funds.

[71] *See* Instruction 8. In a modification from the proposal, we are removing the erroneous reference to Questions 39 and 40 from Instructions 7 and 8, which implied that these questions require advisers to look-through the reporting fund's investments.

[72] We are also specifying that advisers should ''look through'' trading vehicles for all questions, as provided in Instruction 7 and discussed above.

[73] Large hedge fund advisers generally are required to file within 60 calendar days after the end of each calendar quarter and large liquidity fund advisers generally are required to file within 15 calendar days after the end of each calendar quarter. *See* Instruction 9.

[74] AIMA/ACC Comment Letter.

[75] See *infra* section II.F (Effective and Compliance Dates).

All other advisers will continue to file annual updates within 120 calendar days after the end of their fiscal year.[76] Private equity fund advisers will continue to file any required quarterly private equity event reports on a fiscal quarter basis, as applicable.[77] Form PF will continue to require all advisers to use fiscal quarters and years to determine filing thresholds because advisers already make such calculations under 17 CFR 279.1 (''Form ADV''), which requires annual updates based on fiscal year.[78]

Currently, routine fiscal quarter reporting by large hedge fund advisers and large liquidity fund advisers significantly delays the time at which the Commissions and FSOC receive a complete data set for a calendar quarter. For example, large hedge fund advisers whose first fiscal quarter ends on the calendar quarter end of March, would file data covering January, February, and March by the end of May.[79] However, large hedge fund advisers whose fiscal quarter ends in May would not file their March data until the end of July, delaying Commission and FSOC access to full calendar quarter data by all large hedge fund advisers by four months. The adopted changes are designed to provide a more complete data set sooner to improve the efficiency and effectiveness of investor protection efforts and systemic risk assessment. Based on Form ADV data as of December 2022, 99.6 percent of private fund advisers already effectively file Form PF on a calendar basis because their fiscal quarter or year ends on the calendar quarter or year end, respectively.[80] The 0.4 percent of private fund advisers that have a non-calendar fiscal approach, which could cause a temporary data gap, represents approximately 224 private funds, totaling approximately $80 billion in gross asset value. Calendar quarter reporting also will more closely align with reporting on Form CPO–PQR,[81] which requires calendar quarterly reporting, allowing easier integration of these data sets.

In response to a request for comment whether reporting deadlines for large hedge fund advisers to complete their routine annual filing should be shortened to 30 calendar days (from 60 calendar days) after the end of each quarter, one commenter stated that shorter reporting timelines would provide FSOC and the Commissions with the most current information to monitor systemic risk.[82] Another commenter opposed shortened reporting timelines and stated that the existing requirements are already burdensome and requiring shorter deadlines could undermine data quality.[83] After the 2022 Joint Form PF Proposing Release, the SEC adopted amendments to Form PF, which require large hedge fund advisers to file current reports and private equity fund advisers to file event reports upon the occurrence of certain events.[84] The amendment to require calendar quarter, rather than fiscal quarter, basis reporting will improve data comparability and will provide the Commissions with more timely information for those large hedge advisers that currently do not report on a calendar quarter basis.

B. Amendments Concerning Basic Information About the Adviser and the Private Funds It Advises

Each adviser required to file Form PF must complete all or part of section 1. We are adopting amendments to section 1 to provide greater insight into private funds' operations and strategies and to assist in identifying trends, including those that could create systemic risk and which are as such designed to enhance investor protection efforts and systemic risk assessment. The amendments are designed to improve comparability across advisers, improve data quality, and reduce reporting errors, based on our experience with Form PF filings.

1. Amendments to Section 1a of Form PF—Identifying Information

Section 1a requires an adviser to report identifying information about the adviser and the private funds it manages. We are adopting, as proposed, several amendments to collect additional identifying information regarding the adviser, its related persons, and their private fund assets under management.

Legal entity identifiers. We are adopting, as proposed, amendments to the definition of ''LEI'' to exclude the use of any non-LEI identifier, such as an RSSD ID, as a substitute for LEI. Legal entity identifiers, or ''LEIs,'' help identify entities and link data from different sources that use LEIs.[85] These amendments will improve data quality because, based on our experience with the current form, reporting RSSD IDs as LEIs makes it more difficult for our staff to link data efficiently and effectively.

Current Form PF requires advisers to report the LEI for certain entities, such as for the reporting fund, and any parallel funds if they have an assigned LEI. It currently instructs advisers, in the case of an entity that is a financial institution and does not have an assigned LEI, to provide the RSSD ID assigned to the financial institution by the National Information Center of the FRB.[86] We are adopting an amendment to the definition of ''LEI'' to remove the instruction that an adviser provide an RSSD ID with respect to an entity that is a financial institution and that has not been assigned an LEI. Accordingly, an adviser will no longer be permitted to substitute an RSSD ID or any other financial identifier for any requirement in Form PF to provide an LEI, if one has been assigned.[87] An adviser may continue to use an RSSD ID, if the financial institution has one, or another financial identifier for any question that requires an adviser to report other identifying information, where the form of identifying information is not specified.[88]

We are also adopting, as proposed, an amendment to require advisers to provide LEIs for themselves and their ''related persons,'' if they have an LEI.[89]

[76] We also are adopting amendments to the term ''data reporting date'' to reflect this approach. *See* Form PF Glossary of Terms.

[77] *See* Form PF Section 6 and Instruction 9.

[78] *See* Form PF Instructions 1 and 3; Form ADV and [17 CFR 275.204–1] Advisers Act rule 204–1 (amendments to Form ADV).

[79] *See* current Instruction 9 (requiring large hedge fund advisers to update Form PF within 60 calendar days after the end of their first, second, and third fiscal quarters, among other things).

[80] We are presenting data from all private fund advisers, not just those who would file their routine filings on a quarterly basis (*i.e.,* large hedge fund advisers and large liquidity fund advisers), to avoid potentially disclosing proprietary information of individual Form PF filers, and to be inclusive considering that the population of quarterly filers versus annual filers may change over time.

[81] *See* 17 CFR pt 4, app A.

[82] Comment Letter of Mohammed R. (Sept. 9, 2022).

[83] Schulte Comment Letter.

[84] May 2023 SEC Form PF Amending Release, *supra* footnote 4.

[85] Form PF generally defines ''LEI'' as, with respect to any company, the ''legal entity identifier'' assigned by or on behalf of an internationally recognized standards setting body and required for reporting purposes by the U.S. Department of the Treasury's Office of Financial Research or a financial regulator. *See* Form PF Glossary of Terms (definition of ''LEI'').

[86] Currently, if an adviser has not been assigned an LEI and does not have an RSSD ID, then the adviser would leave that line blank.

[87] *See, e.g.,* Questions 5(d) and 7(e).

[88] *See, e.g.,* Question 9(c). We also added ''RSSD ID'' to the Form PF Glossary of Terms and have defined it as the identifier assigned by the National Information Center of the Board of Governors of the Federal Reserve System, if any. *See* Form PF Glossary of Terms.

[89] *See* Question 1. We are also adopting amendments to require advisers to provide the LEI for other entities, if the other entities have one, including internal private funds (see Question 7 and Question 15), trading vehicles (see Question 9), and counterparties (see Question 27 and Question 28). A ''related person'' has the meaning provided in Form ADV. *See* Form PF Glossary of Terms. Form ADV defines a ''related person'' as any

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This amendment will help identify advisers and their related persons and link data from other data sources that use LEI as an identifier.

One commenter supported an expanded use of LEI as a legal identifier in Form PF and stated that more comprehensive inclusion of LEI would create a more complete identification scheme for the Commissions.[90] The commenter also stated that the LEI field in the existing Form PF should be used only for an LEI and not substitute any other identifier for an LEI.[91] The commenter also supported the creation of a separate field for the RSSD ID.[92] Another commenter stated that requirements in Form PF to use a particular financial identifier may increase costs and reduce innovation and competition among financial identifier providers and that increased competition among financial identifiers would improve overall transparency and data quality and reduce costs.[93] As stated above, based on our experience with the current form, however, permitting the reporting of other financial identifiers (namely, RSSD IDs) as LEIs has generally made it more difficult for our staff to link data efficiently and effectively. The amendments to the ''LEI'' definition will thus improve data quality and comparability on Form PF, which supports effective assessment of systemic risk and investor protection efforts. Additionally, Form PF continues to not require an adviser to obtain or use LEI or any other particular financial identifier (other than private fund identification numbers for reporting funds), as our amendments provide only that any identifier that does not meet the definition of ''LEI'' may not be substituted for an LEI where a question requests an LEI. Form PF continues to permit advisers to use other financial identifiers elsewhere on Form PF where the reporting of LEI is either not specified or not required. The amendments to Form PF we are adopting do not require any entity that does not already have an LEI to obtain one and clarifies that an identifier that does not meet the ''LEI'' definition may not be substituted for an LEI where an LEI, if available, is requested on Form PF.

Assets under management. We are adopting, substantially as proposed, amendments to Question 3 to revise how advisers report assets under management attributable to certain private funds. Current Question 3 requires advisers to provide a breakdown of regulatory assets under management and net assets under management. These data are designed to show the size of the adviser and the nature of the adviser's activities. We did not receive comment on the proposed amendments to Question 3. We are amending the instructions to direct advisers to exclude the value of private funds' investments in other internal private funds to avoid double counting of fund of funds assets, as proposed.[94] Advisers are required to include the value of trading vehicle assets because, under the amended instructions for reporting trading vehicle assets, as discussed more fully in section II.A.2 above, advisers are required to ''look through'' the reporting fund's investment in any trading vehicles.[95] We did not receive comment on the proposed change in instructions to Question 3. These amendments are designed to provide a more accurate view of the assets managed by the adviser and its related persons, as well as the general distribution of those assets among various types of private funds, because accurately viewing the scale of these managed assets is important to effectively assess systemic risk and further investor protection efforts.

Explanation of assumptions. We are amending, as proposed, Question 4, which advisers use to explain assumptions that they make in responding to questions on Form PF, to add an instruction directing advisers to provide the question number when the assumptions relate to a particular question. We did not receive comments on this change. This amendment is designed to help assess data more efficiently and improve comparability, based on experience with the form.

We asked in the proposal whether there are other data sources we should use to link entities across forms and to assess data more efficiently. In a further modification from the proposal, we are adopting an amendment to require an adviser to indicate whether it, or any of its related persons, is registered or required to be registered as a CPO and/or a CTA and to provide the legal name of the entity.[96] This information will help more accurately and efficiently identify dual registrants, including those that might be implicated in the identification of threats to financial stability, increase the usefulness and interoperability of the data collected by the Commissions on Form PF and by the CFTC on Form CPO–PQR, and facilitate collaboration between the Commissions with respect to dual registrants.

2. Amendments to Section 1b of Form PF—Concerning All Private Funds

Section 1b requires advisers to report certain identifying and other basic information about each private fund the adviser manages. We are adopting, largely as proposed, amendments to section 1b to require advisers to report additional identifying information about the private funds they manage as well as other basic information about the private funds' assets, financing, investor concentration, and performance. The amendments are designed to provide greater insight into private funds' operations and strategies and assist in identifying trends, which will enhance investor protection efforts and FSOC's systemic risk assessment. At the same time, the amendments will help improve data quality and comparability, based on our experience with Form PF.

Type of private fund. We are adopting several amendments to identify different types of reporting funds more effectively and to help better isolate data according to fund type, in order to allow for more targeted analysis. Currently, advisers indicate a reporting fund's type on the Private Fund Reporting Depository (''PFRD'') filing system, and by filling out particular sections of the form, but they do not report on the form itself the type of fund.[97] We have found instances, however, where advisers have identified a reporting fund differently on Form PF than on Form ADV, even though the definitions of each fund type are the same on both forms. This may be due to error, or may be due to the fund's characteristics changing between deadlines for Form ADV and Form PF. Accordingly, to help prevent reporting errors and help ensure accuracy concerning the reporting fund's type, we are adopting, as proposed, amendments to require advisers to identify the reporting fund by selecting one type of fund from the following list: hedge fund that is not a qualifying hedge fund, qualifying hedge fund, liquidity fund,

advisory affiliate and any person that is under common control with the adviser. *See* Form ADV Glossary of Terms.

[90] *See* GLEIF Comment Letter.

[91] *See id.*

[92] *Id.*

[93] *See* Comment Letter of Bloomberg, L.P. (Oct. 13, 2022) (''Bloomberg Comment Letter'').

[94] *See* Question 3.

[95] *Id.* We have also modified the proposed instructions to Question 3 to remove a reference to the proposed requirement to report trading vehicles on a disaggregated basis, which we are not adopting in this Release. *See also* Form PF Glossary of Terms.

[96] *See* Question 1(c).

[97] For advisers that are also CPOs or CTAs, filing Form PF through PFRD is filing with both the SEC and CFTC. *See* Instruction 3 (instructing advisers to file particular sections of Form PF, depending on their circumstances. For example, all Form PF filers must file section 1 and large hedge fund advisers also must file section 2).

private equity fund, real estate fund, securitized asset fund, venture capital fund, or ''other.'' [98] If an adviser identifies the reporting fund as ''other,'' the adviser will be required to describe the reporting fund in Question 4, including why it would not qualify for any of the other options. We did not receive comments on this amendment. This amendment will further improve data quality and data comparability, based on our experience with Form PF.

In addition, we are adopting, as proposed, amendments to require an adviser to indicate whether the reporting fund is a ''commodity pool,'' which is categorized as a hedge fund on Form PF.[99] Although the CFTC does not, as of the date of this Release, consider Form PF reporting on commodity pools as constituting substituted compliance with CFTC reporting requirements, some CPOs may continue to report such information on Form PF.[100] This amendment will allow for analysis of hedge fund data both with and without commodity pools reported on the form. One commenter opposed the existing default treatment of a commodity pool as a hedge fund for purposes of Form PF and recommended allowing an adviser to categorize a commodity pool in the manner it determines most appropriate.[101] The amendment we are adopting will improve data quality and comparability, based on our experience with Form PF, and enhance our understanding of the hedge fund data collected from Form PF by allowing for analysis of hedge fund data both including and excluding CPOs. Additionally, as it relates to the treatment of commodity pools as hedge funds for reporting purposes, such treatment further aligns the consistency of questions asked across these entities, both on Form PF, as well as on the CFTC's Form CPO–PQR.

Finally, we are adopting, with a modification from the proposal, amendments to require advisers to report whether a reporting fund operates as a UCITS or AIF.[102] One commenter supported the requirement to report whether a fund is a UCITS or AIF and where a fund is domiciled, but not where the fund is ''marketed,'' because a fund could be marketed anywhere and a fund's marketing activity may change over time.[103] Another commenter recommended that references to ''marketing'' be reconsidered, because ''marketing'' is a defined term in the UCITS Directive applicable to a UCITS and in the AIFMD and UK AIFMR applicable to an AIF, and these definitions may differ in meaning from the rule's references to ''marketing.'' [104] This commenter also stated that the references to ''marketing'' in the sense of rule 206(4)–1 and concepts of ''offers'' or ''sales'' under the Securities Act of 1933 would be confusing in this question if the purpose of the proposed question is to determine whether a fund calls itself a money market fund or an equivalent term to prospective investors outside of the United States.[105] After considering comments, we are modifying the question from the proposal to require reporting of a fund that ''offers,'' rather than ''markets,'' itself as a money market fund outside the United States. This modification will more precisely capture the type of conduct that we intend to trigger a reporting requirement, and uses a term that we believe is commonly understood by the industry, and which we accordingly disagree would be confusing.[106] Further, the modification will be less burdensome on advisers than the proposed use of ''marketing'' by clarifying the scope of information required to be reported and requiring a more limited subset of conduct to be reported. For example, a money market fund may engage in certain conduct that constitutes marketing in a particular jurisdiction but not an offering for purposes of the form.

One commenter stated that proposed Question 6(c) would not enhance the Commissions' knowledge about exposures to non-U.S. beneficial owners that is not already included in proposed Question 22 on Form PF.[107] Question 6(c), however, is not intended to elicit the same information about exposures to non-U.S. beneficial owners as proposed Question 22, as discussed further below in section II.B.3. The amendments to Question 6 relate to the conduct and operations of the reporting fund, which are designed to allow the Commissions and FSOC to filter data for more targeted analysis to better understand to what extent and in what jurisdictions a reporting fund operates outside of the United States. This information can help the Commissions better understand the private fund's potential exposure to beneficial owners outside the United States and to identify potential systemic risk resulting from economic conditions or events in particular foreign jurisdictions. This reporting will also help avoid double counting when Form PF data is aggregated with other data sets that include UCITS, AIFs, and money market funds that are offered outside the United States. Proposed Question 22, as discussed further below in section II.B.3, requires an adviser to report more granular information about the fund's beneficial owners, including the percentage of beneficial owners that are non-U.S. persons.[108]

The amendments will improve the data we collect on fund operations and help us better understand a fund's potential exposure to beneficial owners outside the United States. The additional information is necessary for a more targeted analysis of risks presented in the United States from risks presented abroad.[109] Another commenter stated that the proposed amendments do not specify what conduct constitutes operating as a UCITS or how to determine where a fund operates.[110] A UCITS operates under the laws mandated by the member country of its headquarters when it is qualified as a UCITS and authorized by that jurisdiction. This commenter also stated that the meaning of money market fund in Question 6(g) is unclear, particularly for funds that are established and operate as money market funds outside of the United States. For purposes of this question, we have removed reference in Question 6 to

[98] Question 6(a).

[99] Question 6(b). Form PF defines ''commodity pool'' as defined in section 1a(10) of the U.S. Commodity Exchange Act, as amended. *See* Form PF Glossary of Terms.

[100] Previously, the CFTC permitted dually registered CPO-investment advisers to submit Form PF in lieu of certain CFTC reporting requirements. *See* Compliance Requirements for Commodity Pool Operators on Form CPO–PQR (Oct. 9, 2020) [85 FR 71772 (Nov. 10, 2020)] (''Form CPO–PQR Release'').

[101] *See* MFA Comment Letter II.

[102] *See* Questions 6(c) through (f). We are adopting, as proposed, a definition for the term ''UCITS'' as Undertakings for Collective Investment in Transferable Securities, as defined in the UCITS Directive of the European Parliament and of the Council (No. 2009/65/EC), as amended, or as captured by the Collective Investment Schemes (Amendment etc.) (EU Exit) Regulations 2019, as amended. We are adopting, as proposed, a definition for the term ''AIF'' as an alternative investment fund that is not regulated under the UCITS Directive, as defined in the Directive of the European Parliament and of the Council on alternative investment fund managers (No. 2011/61/EU), as amended, or an alternative investment fund that is captured by the Alternative Investment Fund Managers (Amendment etc.) (EU Exit) Regulations 2019, as amended. *See* Form PF Glossary of Terms.

[103] *See* SIFMA Comment Letter.

[104] *See* AIMA/ACC Comment Letter.

[105] *Id.*

[106] ''Offer'' is defined in the Securities Act as ''every attempt or offer to dispose of, or solicitation of an offer to buy, a security or interest in a security, for value.'' 12 U.S.C. 77b(a)(3). For purposes of this question, activity may constitute an ''offer'' under this definition whether or not the offering is subject to the registration requirements of the Securities Act.

[107] AIMA/ACC Comment Letter.

[108] *See* Question 22.

[109] *See* Fact Coalition Comment Letter (discussing the importance of collecting information on exposures outside of the United States).

[110] AIMA/ACC Comment Letter.

the defined term ''money market fund'' as included in the Form PF Glossary of Terms, which continues to have the meaning provided in rule 2a–7 under the Investment Company Act.[111] Instead, in a modification from the proposal, we have amended Question 6 to specify that a money market fund for purposes of Question 6 includes money market funds more generally, including those that operate outside of the United States in accordance with applicable non-U.S. laws, rather than being limited to only ''money market funds'' as defined in Form PF.

Master-feeder arrangements, internal private funds, external private funds, and parallel fund structures. We are adopting, as proposed, amendments to Form PF to require advisers to report identifying information about master-feeder arrangements and other private funds (*e.g.,* funds of funds), including internal private funds, and external private funds.[112] These changes to the form reflect that advisers will be required to report components of master-feeder arrangements and parallel fund structures separately, as discussed more fully in section II.A.1 above. Form PF currently requires advisers to report identifying information about parallel funds, and will continue to do so under the amended Form PF.[113] The amendments will also require advisers to report the value of the reporting fund's investments in other private funds (*e.g.,* for funds of funds) in more detail than is currently required.[114] Specifically, the amendments will require advisers to report the value of the reporting fund's equity investments in external private funds and internal private funds (including the master fund and each internal private fund), which together make up the total investments in other private funds.[115] These amendments are designed to help map complex fund structures and cross reference private fund information more effectively across Form PF filings, in order to provide more complete and accurate information about each fund's risk profile.

In connection with these amendments, in the Form PF Glossary of Terms, we are removing the terms ''investments in external private funds'' and ''investments in internal private funds,'' and replacing them with the terms ''external private funds'' (*i.e.,* private funds that neither the adviser nor the adviser's related persons advise) and ''internal private funds'' (*i.e.,* private funds that the adviser or any of the adviser's related persons advise), respectively. The definitions do not direct advisers to exclude ''cash management funds,'' as is currently the case under the terms being removed, because we have observed that advisers determine whether a fund is a cash management fund inconsistently for purposes of Form PF, which reduces data quality.

As discussed more fully above in section II.A.1, some commenters supported requiring disaggregated reporting of master-feeder arrangements and parallel fund structures, stating that it will allow the Commissions to identify potential systemic risk more effectively and increase the transparency of private fund holdings.[116] Other commenters opposed the proposed amendments to require reporting of the components of parallel funds and master-feeder funds separately.[117] We did not however receive specific comment on the proposed definitional changes. One commenter recommended including an exclusion in Questions 15(a) and 15(b), similar to the exclusion in Question 15(c), to avoid potentially double counting any master funds that are external private funds.[118] We believe the instruction in Question 15(c) to exclude any funds disclosed in Question 15(b) is sufficient to avoid any double counting of assets in this set of questions.[119] These amendments will improve data quality and comparability, based on our experience with Form PF and in light of adopted changes to master-feeder and parallel fund structure reporting on Form PF.

Withdrawal or redemption rights. We are also adopting, with modifications from the proposal, as specified below, amendments to change how advisers report withdrawal and redemption rights. Form PF currently requires only large hedge fund advisers to report whether each qualifying hedge fund provides investors with withdrawal or redemption rights in the ordinary course.[120] We proposed adding a new Question 10(a) which would generally require all advisers to report whether a reporting fund provides investors with withdrawal and/or redemption rights in the ordinary course.[121] In a modification from the proposal, we are adopting a modified Question 10, which instead requires all advisers to indicate whether the reporting fund is an open-end private fund in Question 10(a) or a closed-end private fund in Question 10(b).

We are relatedly adopting new defined terms for ''open-end private fund'' and ''closed-end private fund'' and modifying Question 10 to ask whether the reporting fund is an ''open-end private fund'' or ''closed-end private fund,'' rather than whether the reporting fund provides investors with withdrawal and/or redemption rights in the ordinary course. In discussing certain aspects of the proposal, some commenters distinguished between open-end and closed-end funds.[122] One commenter indicated that the term ''closed-end fund'' refers to funds that do not offer withdrawal or redemption rights in the ordinary course.[123] We are defining a ''closed-end private fund'' as any private fund that only issues securities, the terms of which do not provide a holder with any right, except in extraordinary circumstances, to withdraw, redeem, or require the repurchase of such securities, but which may entitle holders to receive distributions made to all holders *pro rata.*[124] We are defining an ''open-end private fund'' as a private fund that offers redemption rights to its investors in the ordinary course, which may be paid in cash or in kind, irrespective of redemption frequency or notice periods and without regard to any suspensions, gates, lock-ups, or side pockets that may be employed by the fund.[125] These terms are commonly used in the market,

[111] *See* Form PF Glossary of Terms (definition of ''money market fund'').

[112] For master-feeder arrangements, advisers will be required to report the name of the feeder fund, its private fund identification number, and whether the feeder fund is a separate reporting fund or a disregarded feeder fund. For internal private funds that invest in the reporting fund, advisers will be required to report the name of the internal private fund, its LEI, if it has one, and its private fund identification number. *See* Question 7. If the reporting fund invests in external private funds, advisers will be required to report the name of the master fund, its private fund identification number, and the master fund's LEI, if it has one. If the reporting fund invests in internal private funds, advisers will be required to report the internal private fund's name, its private fund identification number, and its LEI, if it has one. *See* Question 15.

[113] *See* Question 7 and Question 8.

[114] *See* Question 15.

[115] *Id.*

[116] *See, e.g.,* Better Markets Comment Letter; NASAA Comment Letter.

[117] *See, e.g.,* AIC Comment Letter I; AIMA/ACC Comment Letter; MFA Comment Letter II.

[118] *See* AIMA/ACC Comment Letter.

[119] We do not believe an instruction in Question 15(c) to exclude funds reported in Question 15(a) is necessary because Question 15(a) relates to external private funds only.

[120] *See* current Question 49(a).

[121] *See* proposed Question 10(a).

[122] *See, e.g.,* AIMA/ACC Comment Letter; Comment Letter of Ropes & Gray LLP (Oct. 11, 2022) (''Ropes & Gray Comment Letter'').

[123] AIMA/ACC Comment Letter.

[124] *See* Form PF Glossary of Terms (definition of ''closed-end private fund''). The definition of ''closed-end private fund'' is adapted from the definition of ''venture capital fund'' in rule 203(l)–1 under the Advisers Act. *See* 17 CFR 275.203(l)–1.

[125] *See* Form PF Glossary of Terms (definition of ''open-end private fund'').

based on staff experience, and will be used in place of the existing question that asks whether the reporting fund provides investors with withdrawal/redemption rights in the ordinary course.

Although the proposed question and the adopted question lead to substantively identical results in most cases, the adopted question will improve data quality by more precisely specifying what is meant by ''offer[ing] withdrawal and/or redemption rights in the ordinary course'' and, accordingly, how an adviser should classify a reporting fund that offers limited withdrawal or redemption rights. In a modification from the proposal, an adviser that selects in Question 10 that the reporting fund is neither an open-end private fund nor a closed-end private fund will be required to provide a detailed explanation of these responses in Question 4.[126] We requested comment on whether we should include an additional category of ''other'' withdrawal and/or redemption frequency.[127] Some commenters stated that the proposed question 10 was unclear on how to report withdrawal and redemption rights properly, particularly for funds with rights that do not fit within a single frequency category.[128] Instead of including an ''other'' category, as stated above, advisers that respond ''no'' to both Questions 10(a) and 10(b) will be required to provide a detailed explanation of these responses in Question 4, which will enable us to understand the circumstances of the fund's withdrawal and/or redemption rights and will improve data quality. It will also help an adviser that might otherwise feel constrained by these two categories if the fund it advises does not fit into either. We are requiring advisers to identify whether a reporting fund is an open-end private fund or a closed-end private fund to inform the Commissions and FSOC better of all reporting funds' susceptibility to stress related to investor redemptions, in order to help identify more effectively how widespread the potential stress may be.[129]

In a modification from the proposal, if the reporting fund is an open-end private fund under Question 10(a), the adviser will be required to indicate (i) how often withdrawals or redemptions are permitted by selecting from a list of categories pursuant to Question 10(c) [130] and (ii) what percentage of the reporting fund's net asset value may be, or is, subject to a suspension of, or material restrictions on, investor withdrawals/redemptions by an adviser or fund governing body pursuant to Question 10(d).[131] The adviser will be required to report this information regardless of whether there are notice requirements, gates, lock-ups, or other restrictions on withdrawals or redemptions.[132] These amendments will allow the Commissions and FSOC to identify more effectively the reporting funds that may be affected by investor withdrawals during certain market events and/or are vulnerable to failure as a result of investor redemptions. This information will also provide insight into other data that all reporting funds report. For example, we understand that closed-end private equity funds may have certain patterns of subscriptions and withdrawals, despite not offering redemption rights in the ordinary course, and also may report performance to investors and prospective investors as an internal rate of return as opposed to as a measure of the changes in the fund's portfolio market value.

One commenter stated that expanding the classes of private funds that are required to disclose withdrawal and redemption rights would allow FSOC to better identify systemic risks, particularly resulting from market events.[133] Another commenter opposed the proposed requirement for all advisers to report on withdrawal and redemption rights, asserting that the data would be of limited benefit for systemic risk monitoring due to the inclusion of data from smaller funds, as well as that the types of withdrawal and redemption restrictions referenced in proposed Question 10(b) (which has been redesignated as Question 10(c)) do not reflect the practices of many hedge funds.[134] A private fund of any size that provides for withdrawal or redemption rights may be affected by increased investor withdrawals during certain market events and/or vulnerable to failure as a result of investor redemptions. This reporting will allow the Commissions and FSOC to assess withdrawal and redemption patterns to identify potential signals of stress at a particular fund or across many funds, or related to a particular investment strategy or strategies, which is relevant for assessing broader systemic risk. Information on withdrawal and redemption rights from all private funds, including smaller private funds or funds that are not included in the definition of a ''hedge fund,'' will improve FSOC's ability to monitor potential systemic risk and support the Commissions' investor protection efforts.

Some commenters stated that the proposed Question 10(b) (which has been redesignated as Question 10(c)) does not address how to report a fund with multiple types of redemption rights.[135] Some commenters recommended permitting an adviser to select multiple options for withdrawal and redemption rights in Question 10.[136] However, it would not support or enhance our data analysis efforts to modify Question 10(c) to allow for multiple selections, given that other questions on Form PF require reporting of a fund's withdrawal and redemption activity.[137] Instead, we are modifying Question 10(c) to ask for the interval on which withdrawals or redemptions are ''most commonly'' permitted (*i.e.,* with respect to most investors). We also encourage an adviser to report any additional details on a fund's withdrawal or redemption schedule in response to Question 4, as appropriate.

Trading vehicles. We are adopting, with modifications from the proposal as specified below, amendments to require advisers to provide identifying information for any trading vehicle in

[126] *See* Questions 10(a) and 10(b).

[127] *See* 2022 Joint Form PF Proposing Release *supra* footnote 4, at 32.

[128] *See, e.g.,* AIMA/ACC Comment Letter; SIFMA Comment Letter.

[129] To implement this change, we have moved current Questions 49(a) through (e) from section 2b, which required only large hedge fund advisers to report withdrawal and redemption information about qualifying hedge funds, to section 1b, which requires all advisers to report withdrawal and redemption information about all the reporting funds they advise, and we have redesignated Questions 49(a) through (e) as part of new Question 10.

[130] *See* Question 10(c). The categories are: (1) on any business day, (2) at intervals of at least two business days and up to a month, (3) at intervals longer than monthly up to quarterly, (4) at intervals longer than quarterly up to annually, and (5) at intervals of more than one year.

[131] We are redesignating current Questions 49(a) through (e) as new Question 10. Currently, all advisers to qualifying hedge funds that provided investors with withdrawal/redemption rights in the ordinary course are required to respond to Questions 52(a) through (e) in section 2(b). We are moving proposed Questions 52(a) through (e) to section 1(b) and redesignating it as part of new Question 10, so that all advisers to open-end private funds, rather than only advisers to qualifying hedge funds that provide investors with withdrawal/redemption rights in the ordinary course, will need to respond to this question.

[132] For example, if the reporting fund allows quarterly redemptions that are subject to a gate, then the adviser would select ''at intervals longer than monthly up to quarterly.''

[133] *See* Fact Coalition Comment Letter.

[134] *See* Schulte Comment Letter.

[135] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter; USCC Comment Letter.

[136] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II.

[137] *See, e.g.,* Question 14.

which the reporting fund holds assets, incurs leverage, or conducts trading or other activities.[138] Advisers will be required to disclose the trading vehicle's legal name; LEI, if it has one; and any other identifying information about the trading vehicle, such as the RSSD ID, if it has any. In a change from the proposal, an adviser will also be required to specify if the reporting fund holds assets through a trading vehicle, incurs leverage through a trading vehicle, or conducts trading or other activities through a trading vehicle.[139] As discussed above, the final amendments will include specific questions to target specified information related to a reporting fund's use of trading vehicles, leveraging information used to answer Questions 9(a) through (c), as opposed to requiring a full separate reporting on Form PF for trading vehicles.[140] These questions are intended to identify what conduct requires the vehicle to be reported as a trading vehicle for purposes of Form PF and will help improve our understanding of a reporting fund's trading vehicle use. This amendment will help the Commissions and FSOC understand the reporting fund's activities, including how it interacts with the market if the fund trades through a trading vehicle, as well as its related counterparty exposures. The identifying information will also allow comparisons of Form PF data with data from other sources that use such information to identify entities. Enhancing the ability to compare Form PF data in this way, including with respect to the use of trading vehicles, will provide a more comprehensive view of the market that enhances systemic risk assessment and our investor protection efforts.

As discussed more fully above in section II.A.2 of this Release, we received comments regarding proposed Instruction 7 regarding the proposed disaggregated reporting of trading vehicles. One commenter recommended that a threshold question of whether the reporting fund uses a trading vehicle should be added to proposed Question 9.[141] Such an instruction is not necessary because it is generally understood that an adviser may leave blank any inapplicable question.

Gross asset value and net asset value. We are adopting, with changes from the proposal, several amendments to the way advisers report gross asset value and net asset value. We are adopting amendments to require large hedge fund advisers and large liquidity fund advisers to report net asset value and gross asset value (or, if such values are not calculated monthly, the reporting fund aggregate calculated value and the gross reporting fund aggregate calculated value, respectively) as of the end of each month of the reporting period in their quarterly filings, rather than only reporting the information as of the end of the reporting period, as Form PF currently requires.[142] This amendment is designed to facilitate analysis of other monthly Form PF data, including certain fund performance and risk metrics.[143]

Some commenters expressed concerns that calculating net asset value (or gross asset value) on a monthly basis would be overly burdensome.[144] Another commenter asserted that the net asset value or gross asset value of a fund or a fund's investments may not be available on a monthly basis in the case of investments made into other funds or entities that are not advised by the filer or its related persons, in which case the timing of the reporting may not match a monthly reporting obligation.[145] One commenter recommended requiring reporting on net asset value and gross asset value on a quarterly, rather than monthly, basis to lessen the burden on advisers.[146]

Monthly asset value data is important to allow analysis of other monthly basis data collected on Form PF for systemic risk monitoring and to support our investor protection efforts. However, after considering comments, and in a change from the proposal, an adviser may report in response to Questions 11 and 12 a fund's ''gross reporting fund aggregate calculated value'' (''GRFACV'') or ''reporting fund aggregate calculated value'' (''RFACV''), rather than gross asset value or net asset value, respectively and as applicable, if its net asset value and gross asset value are not calculated on a monthly basis.[147] Permitting an adviser to report GRFACV or RFACV will reduce the need for advisers to report the net asset value or gross asset value on a monthly basis, as proposed. As discussed more fully below, in connection with proposed amendments to fund performance reporting, we proposed adding a requirement for certain advisers to report additional performance information, including RFACV. We are adding the option for advisers to report RFACV for Question 12 and GRFACV for Question 11 because use of RFACV and GRFACV will reduce burdens on advisers while allowing us to continue to receive useful monthly valuation data to allow for effective systemic risk monitoring and investor protection efforts.[148] RFACV and GRFACV may be calculated using the adviser's own methodologies or those of its service providers, provided that the methodologies used to calculate RFACV and GRFACV are consistent with information reported internally.[149] Advisers will be required to indicate whether the reported data represents RFACV or GRFACV, rather than a net asset value or gross asset value, as applicable, to maintain data comparability. Requiring monthly data will help facilitate analysis of the other monthly data reported on Form PF, such as fund performance, and help identify trends for systemic risk analysis and investor protection efforts.

We also are adopting, as proposed, amendments to add new Question 13, which requires advisers to separately

[138] *See* Question 9.

[139] *See* Questions 9(d) through (f).

[140] *See supra* section II.A.2 of this Release for further discussion.

[141] AIMA/ACC Comment Letter.

[142] *See* Questions 11 and 12. We also are adopting amendments to the instructions in Question 11 to correspond with the instructions that no longer allow advisers to aggregate master-feeder arrangements, as discussed above. In a modification from the proposal, we are adding an instruction to specify that for feeder funds responding to Questions 11 and 12, the gross asset value or gross reporting fund aggregate calculated value and net asset value or reporting fund aggregate calculated value calculations should be inclusive of its equity holdings in the master fund, along with its other holdings, to more accurately represent the value of the feeder fund's holdings.

[143] *See, e.g.,* Question 23 (requiring all private fund advisers to report monthly performance data, to the extent such results are calculated for the reporting fund).

[144] *See, e.g.,* MFA Comment Letter II.

[145] *See* AIMA/ACC Comment Letter.

[146] *See* MFA Comment Letter II.

[147] The amendments to Form PF adopted in the May 2023 SEC Form PF Amending Release, *supra* footnote 4, adopted a definition for ''reporting fund aggregate calculated value.'' RFACV is defined as every position in the reporting fund's portfolio, including cash and cash equivalents, short positions, and any fund-level borrowing, with the most recent price or value applied to the position for purposes of managing the investment portfolio. *See* Form PF Glossary of Terms (definition of ''reporting fund aggregate calculated value''). Because we are now, after considering comments, adding the new GRFACV term, we are also modifying the definition of RFACV to clarify that it is a signed (*i.e.,* positive or negative) value where all positions are summed. GRFACV, which is used solely in Question 11 is calculated in the same manner as RFACV, except that instead of summing each position's signed value, GRFACV converts each position's value to an absolute value prior to summing these absolute values.

[148] This change is also consistent with the recent amendments adopted by the SEC which require a large hedge fund adviser to monitor and in certain instances report, the fund's RFACV in compliance with its current reporting obligation. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4.

[149] *See* Form PF Glossary of Terms. Advisers will continue to be required to report gross asset value and net asset value as of the end of the reporting period. See current Questions 8 and 9, which have been redesignated as Questions 11(a) and 12(a).

report the value of unfunded commitments included in the net and gross asset values reported in Questions 12 and 11.[150] Advisers that provide an RFACV or GRFACV in response to Questions 12 and 11 will report the value of unfunded commitments that are included in the RFACV or GFRACV figures. Current Questions 8 and 9 (which have been replaced by Questions 11 and 12) require valuations based on the instruction in Form ADV for calculating regulatory assets under management, which requires advisers to include the amount of any unfunded commitments.[151] This approach reflects that, in the early years of a private fund's life, its adviser typically earns fees based on the total amount of capital commitments, which we presume reflects compensation for efforts expended on behalf of the fund in preparation for the investments.[152] The asset value calculations in Questions 11 and 12 should include unfunded commitments, so that Form PF data is comparable to Form ADV data. However, there are circumstances where understanding the amount represented by unfunded commitments will enhance our understanding of changes to a reporting fund's net and gross asset value over time, inform us of trends, and improve data comparability over the life of the fund. For example, knowing the value of uncalled commitments will help the Commissions and FSOC more accurately identify the leverage of a fund with uncalled commitments. We did not receive specific comment on the proposed addition of Question 13. We continue to believe that receiving this information on uncalled commitments will improve data accuracy and comparability, which is important for effective systemic risk assessment and investor protection efforts.

Inflows and outflows. We are adopting, as proposed, an amendment to add a question requiring advisers to report information concerning the reporting fund's activity, including contributions to the reporting fund, as well as withdrawals and redemptions, which includes all withdrawals, redemptions, or other distributions of any kind to investors.[153] Amended Form PF specifies that, for purposes of the question, advisers must include all new contributions from investors and exclude contributions of committed capital that they have already included in gross asset value calculated in accordance with Form ADV instructions.[154] Large hedge fund advisers and large liquidity fund advisers are required to provide this information for each month of the reporting period. This requirement will facilitate analysis of other monthly Form PF data, including certain fund performance and risk metrics, improve data accuracy, and allow the Commissions and FSOC to analyze data more efficiently. Inflows and outflows inform the Commissions and FSOC of the relationship between flows and performance, changes to net and gross asset value, as well as trends in the private fund industry. Accordingly, this question will provide a more accurate baseline understanding of inflows and outflows, so the Commissions and FSOC can, for example, more accurately assess how much the private fund industry has grown from flows versus performance. Inflows and outflows also can indicate funding fragility, which can have systemic risk implications. Therefore, this amendment will provide more accurate data of inflows and outflows for systemic risk assessment and investor protection efforts, including identifying activity that may not match investor disclosures.

One commenter stated that recent global events have demonstrated the importance of FSOC's assessment of the potential systemic risks created by inflows into private investment markets.[155] Another commenter stated that reporting inflows and outflows on a monthly basis would create additional burdens with limited benefits for systemic risk monitoring purposes and recommended an annual reporting requirement.[156] However, based on our experience, receiving fund activity data on a monthly basis for large hedge fund advisers is important for systemic risk analysis and investor protection efforts. Currently, large hedge fund advisers file quarterly but only report changes in inflows or outflows on an annual basis, which causes this data to be stale and less effective than more frequently reported data for monitoring systemic risk. We also currently cannot differentiate between changes in value resulting from performance and changes in value resulting from inflows and outflows. Inflow and outflow information on a monthly basis will allow us to better understand the meaning of interim changes in investment inflows and outflows that may be relevant to systemic risk assessment. We also understand that advisers generally maintain this information on a monthly basis for internal recordkeeping purposes.

Base currency. We are adopting, as proposed, amendments to require all advisers to identify the base currency of all reporting funds, rather than only requiring large hedge fund advisers to identify this information for qualifying hedge funds.[157] As discussed more fully in section II.D below, Instruction 15 will continue to require all advisers to convert monetary values reported on the form to U.S. dollars for any reporting fund that uses a base currency other than U.S. dollars.[158] The Commissions and FSOC are able to currently identify whether monetary value information has been converted from another base currency and whether there may have been inconsistencies in the converted information only with respect to qualifying hedge funds reported by large hedge fund advisers in response to current Question 31. Therefore, this change will allow the Commissions and FSOC to interpret more accurately responses to questions regarding foreign exchange exposures and the effect of changes in currency rates on all reporting fund portfolios, which will aid systemic risk assessment and investor protection efforts across all reporting fund portfolios.

Although we received comments regarding the proposed amendment to require advisers to report using U.S.

[150] We are adopting amendments to the definition of ''unfunded commitments'' as committed capital that has not yet been contributed to the reporting fund by investors. Currently, the definition refers only to private equity funds, and we are adopting amendments to amend the definition to refer to all reporting funds. Form PF defines ''committed capital'' as any commitment pursuant to which a person is obligated to acquire an interest in, or make capital contributions to, the private fund. *See* Form PF Glossary of Terms.

[151] Form PF requires advisers to calculate gross asset value and net asset value using regulatory assets under management, a regulatory metric from Form ADV. See ''gross asset value'' and ''net asset value'' as defined in Form PF Glossary of Terms; Form ADV: Instructions for Part 1A, Instruction 5.b. An adviser must calculate its regulatory assets under management on a gross basis, that is, without deduction of any outstanding indebtedness or other accrued but unpaid liabilities. In addition, an adviser must include the amount of any uncalled capital commitments made to a private fund managed by the adviser.

[152] Rules Implementing Amendments to the Investment Advisers Act of 1940, Advisers Act Release No. 3221 (June 22, 2011) [76 FR 42950, 42956 (July 19, 2011)], at text accompanying n.90.

[153] *See* Question 14.

[154] Form PF, as amended, cites to Form ADV, Part 1A Instruction 6.e.(3).

[155] Fact Coalition Comment Letter.

[156] Schulte Comment Letter.

[157] To implement this, current Question 31 has been redesignated as Question 17 and has been moved from existing section 2b, which required only large hedge fund advisers to report information about qualifying hedge funds, to section 1b, which requires all advisers to report information about all the reporting funds they advise. *See* Question 17.

[158] *See* Instruction 15. We are revising, as proposed, Instruction 15 to provide additional instructions concerning currency conversions. *See* section II.D (Amendments to Enhance Data Quality) of this Release.

dollars for any private fund that has a base currency other than U.S. dollars,[159] we did not receive comments to the proposed amendment to require all advisers to report the reporting fund's base currency. We continue to believe our adopted approach will allow for more accurate responses to other questions on Form PF regarding currency exposures and improve data comparability to aid systemic risk assessment and our investor protection efforts.[160]

Borrowings and types of creditors. We are adopting, largely as proposed, amendments to revise how advisers report the reporting fund's ''borrowings.'' First, we are revising the term ''borrowings'' to (1) specify that it includes ''synthetic long positions,'' which is defined in the Glossary of Terms, and (2) provide a non-exhaustive list of types of borrowings.[161] This reporting approach is consistent with SEC staff Form PF Frequently Asked Questions.[162] This amendment is designed to improve data quality, based on our experience with the form.

Some commenters stated that it is not clear how an adviser should report cross-collateralized agreements.[163] A modification to the instructions to address this comment is not warranted. The instructions to Questions 26 and 41,[164] as applicable, specify how margin for these arrangements should be reported. For example, the instructions to these questions indicate that the adviser is to classify borrowing and collateral received and lending and posted collateral according to type and the governing legal agreement, such as a prime brokerage or other brokerage agreement, for cash margin and securities lending and borrowing. Additionally, the instructions for each of these questions allow respondents to indicate whether cross margining is in effect and indicate how to treat the collateral in such cases. One commenter stated that the Commissions should establish a threshold for when a position is considered ''deep-in-the-money'' and recommended including a definition for ''deep-in-the-money'' positions in the definitions of ''synthetic long position'' and ''synthetic short position.'' [165] In consideration of this comment and in order to improve data quality, we are revising the definitions of the ''synthetic long position'' and the ''synthetic short position'' to more clearly specify, as an example, that a position with a delta of 98% or higher is considered to be ''deep-in-the-money.'' [166] Based on our experience, we believe that a delta of 98% or higher is typically the most appropriate threshold for both long and short expiry option exposures for reporting purposes and will furthermore be generally consistent with advisers' expectations and accommodate their internal practices, where many advisers already use a lower threshold. Although other thresholds could potentially be used, a delta of 98% or higher will generally provide us with more reliable and accurate information for systemic risk assessment purposes. If set lower than this level, the threshold could trigger inappropriately due to the impact of the delta's rate of change (*i.e.,* its gamma) and capture options that should not constitute synthetic short or long positions, such as options with little time left to expiry that may be close to their strike level. If set higher (*e.g.,* to 99%), the threshold could miss longer-dated options that should constitute synthetic short positions, but where the lengthy time to expiry allows the possibility that the options will go unexercised, such that the threshold will not be met, and the options will inappropriately be not included.

Second, we are adopting amendments to Question 18, which requires advisers to report the value of the reporting fund's borrowings and the types of creditors, to require advisers to indicate whether a creditor is based in the United States and whether it is a ''U.S. depository institution,'' rather than a ''U.S. financial institution'' as is currently required.[167] This amendment will make the categories more consistent with the categories that the FRB uses in its reports and analysis, which will enhance systemic risk assessment. Advisers are not required to distinguish between non-U.S. creditors that are depository institutions and those that are not. We understand that it is difficult for advisers to distinguish non-U.S. creditors by type, which can result in inconsistent data that is less valuable for analysis. We did not receive specific comment on this amendment.

Fair value hierarchy. We are adopting, largely as proposed, a number of amendments to revise how advisers report fair value hierarchy in Question 20, to improve data quality and better understand the reporting fund's complexity and valuation challenges.[168]

First, we are adopting amendments that require advisers to indicate the date on which the categorization was performed. This amendment is designed to show how old the data is. Some advisers report current fair value hierarchy, while others report a prior year's fair value hierarchy if the current data is not yet available.[169] This can

[159] *See infra* section II.D of this Release.

[160] As discussed more fully below in section II.C.2.a, we are also adopting amendments to require currency exposure reporting for qualifying hedge fund advisers.

[161] ''Borrowings'' include, but are not limited to (1) cash and cash equivalents received with an obligation to repay; (2) securities lending transactions (count cash and cash equivalents and securities received by the reporting fund in the transaction, including securities borrowed by the reporting fund for short sales); (3) repo or reverse repo (count cash and cash equivalents and securities received by the reporting fund); (4) negative mark-to-market of derivative transactions from the reporting fund's point of view; and (5) the gross notional value of ''synthetic long positions.'' The term ''synthetic long position'' is defined in the Form PF Glossary of Terms. We are adopting, with modifications from the proposal, the definition of ''synthetic long position'' based on our understanding of the instruments and to help ensure data quality to aid comparability.

[162] *See* SEC staff Form PF Frequently Asked Questions, *available at https://www.sec.gov/divisions/investment/pfrd/pfrdfaq.shtml* (''Form PF Frequently Asked Questions''). *See* Form PF Frequently Asked Question 12.1 (which provides a non-exhaustive list of types of borrowings).

[163] *See* AIMA/ACC Comment Letter; USCC Comment Letter.

[164] For hedge funds, other than qualifying hedge funds, advisers complete Question 26. For qualifying hedge funds, advisers complete Question 41.

[165] MFA Comment Letter II.

[166] *See* Form PF Glossary of Terms (definitions of ''synthetic long position'' and ''synthetic short position'').

[167] *See* Question 18. Form PF defines ''U.S. depository institution'' as any U.S. domiciled depository institution, including any of the following: (1) a depository institution chartered in the United States, including any Federally-chartered or State-chartered bank, savings bank, cooperative bank, savings and loan association, or an international banking facility established by a depositary institution chartered in the United States; (2) banking offices established in the United States by a financial institution that is not organized or chartered in the United States, including a branch or agency located in the United States and engaged in banking not incorporated separately from its financial institution parent, United States subsidiaries established to engage in international business, and international banking facilities; (3) any bank chartered in any of the following United States affiliated areas: U.S. territories of American Samoa, Guam, and the U.S. Virgin Islands; the Commonwealth of the Northern Mariana Islands; the Commonwealth of Puerto Rico; the Republic of the Marshall Islands; the Federated States of Micronesia; and the Trust Territory of the Pacific Islands (Palau); or (4) a credit union (including a natural person or corporate credit union). Form PF defines ''U.S. financial institution'' as any of the following: (1) a financial institution chartered in the United States (whether Federally-chartered or State-chartered); (2) a financial institution that is separately incorporated or otherwise organized in the United States but has a parent that is a financial institution chartered outside the United States; or (3) a branch or agency that resides outside the United States but has a parent that is a financial institution chartered in the United States. *See* Form PF Glossary of Terms.

[168] We have redesignated current Question 14 to Question 20.

[169] Advisers are not required to update information that they believe in good faith properly responded to Form PF on the date of filing even if that information is subsequently revised for purposes of their recordkeeping, risk management,

cause confusion when analyzing the data, because the fair value hierarchy data concerns a different time period than the other data advisers report on Form PF. Therefore, we believe that adding a categorization date will help prevent the data from being incorrectly categorized as applying to the wrong time period, and in turn, will allow the Commissions and FSOC to correlate data to other Form PF data and market events more accurately. We did not receive specific comment on this amendment.

Second, we are adopting amendments to direct advisers to report the absolute value of all liabilities. Currently, advisers report liabilities inconsistently, with some reporting absolute values and others reporting negative values. This inconsistency causes errors when the Commissions and FSOC aggregate this data, and the amended instruction will help reduce aggregation errors. We did not receive specific comment on this amendment.

Third, we are adopting amendments to direct advisers to provide an explanation in Question 4 if they report assets as a negative value. We have found that some advisers have reported negative values for assets in error.[170] Therefore, this instruction is designed to reduce inadvertent errors. We did not receive specific comment on this amendment.

Fourth, we are adopting amendments to require advisers to separately report cash and cash equivalents. Currently, Form PF does not explain where advisers must report cash and cash equivalents in current Question 14. SEC staff have recommended that advisers generally should report cash in the cost based column and cash equivalents in the applicable column in the fair value hierarchy or the cost based column, depending on the nature of the cash equivalents, but now we are adding a separate column for cash and cash equivalents.[171] The amended categorization is designed to differentiate reported holdings of cash and cash equivalents from harder-to-value assets that may be valued at cost, and in turn, improve data quality and comparability. We did not receive specific comment on this amendment.

Fifth, we are adopting amendments to the definition of ''cash and cash equivalents.'' The current definition of ''cash and cash equivalents'' includes ''government securities.'' [172] When reporting cash and cash equivalents, some advisers may include government securities with longer maturities, while others do not, which results in inconsistent reporting and may obscure our and FSOC's understanding of fund exposures. Therefore, to improve data quality, we are removing government securities from the definition of ''cash and cash equivalents'' and presenting government securities as its own line item in the Form PF Glossary of Terms.[173] Some commenters opposed the proposed removal of government securities from the definition of ''cash and cash equivalents,'' stating that the revised definition is inconsistent with market practice and internal fund practices, which generally treat government securities as cash equivalents.[174] One commenter recommended that the definition of ''cash and cash equivalents'' should include U.S. treasury securities with maturity of 90 days or less to the extent that the adviser treats these as cash equivalents.[175] We continue to believe that the removal of all government securities from the definition of ''cash and cash equivalents'' and requiring reporting of government securities holdings separately will improve data quality and our and FSOC's understanding of fund holdings. The amended definition is intended to provide more granular detail on a fund's exposure and is not intended to change any commercial understanding or accounting treatment of cash equivalents or result in any fund investment changes. It is appropriate to require advisers to list *all* government securities, including U.S. treasury securities with maturity of 90 days or less, under a separate category because they represent a different asset type and market that are relevant for purposes of assessing systemic risk.

Further, we are adopting, as proposed, an amendment to the term ''cash and cash equivalents'' that directs advisers to exclude digital assets when reporting cash and cash equivalents.[176] One commenter recommended that the Commissions clarify how to report an asset that may be reasonably included in multiple categories and stated that, digital assets, as proposed to be defined, may overlap with multiple reporting categories.[177] This amendment to the ''cash and cash equivalent'' definition will facilitate appropriate classifications.

We are adopting amendments to add instructions directing advisers about how to report data if their financial statement's audit is not yet completed when Form PF is due. The instructions state that advisers should use the estimated values for the fiscal year and explain that the information is an estimate in Question 4. The instructions also provide that the adviser may, but is not required to, amend Form PF when the audited financial statements are complete.[178] The instructions are consistent with responses to Form PF Frequently Asked Questions and are designed to provide the Commissions and FSOC with more recent information regarding the reporting fund than may be possible if the reporting fund relied solely on audited financial statement information (*i.e.,* the reporting fund's previous fiscal year's audited financial statements).[179] Given that advisers file Form PF sometimes months after their quarter and year ends, depending on their size and the type of funds they advise, the amended instruction balances reporting burdens with the need for more timely information for assessing potential systemic risk and investor protection concerns. We did not receive specific comment on this amendment.

Beneficial Ownership of the Reporting Fund. Form PF currently requires advisers to specify the approximate percentage of the reporting fund's equity that is beneficially owned by different groups of investors. We are redesignating current Question 16 as Question 22 and amending the question, as proposed, to require advisers to provide more granular information regarding the following groups of beneficial owners.

or investor reporting (such as estimates that are refined after completion of a subsequent audit). *See* Instruction 16.

[170] We recognize that there may be cases when advisers correctly report negative values, such as when subtracting fund of fund investments.

[171] *See* Form PF Frequently Asked Question 14.3, Form PF Frequently Asked Questions, *supra* footnote 162.

[172] Form PF defines ''government securities'' as (1) U.S. Treasury securities, (2) agency securities, and (3) any certificate of deposit for any of the foregoing. *See* Form PF Glossary of Terms.

[173] We are adopting corresponding amendments to the definition of ''unencumbered cash'' to reflect that ''government securities'' are a distinct term from ''cash and cash equivalents.'' This amendment does not change the meaning of the term ''unencumbered cash.'' *See* Form PF Glossary of Terms.

[174] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II.

[175] MFA Comment Letter II.

[176] As discussed further in section II.B.3 of this Release, in a modification from the proposal, we are not adopting the proposed definition of ''digital asset.''

[177] MFA Comment Letter II.

[178] Instruction 16 continues to provide that an adviser is not required to update information that it believes in good faith properly responds to Form PF on the date of filing, even if that information is subsequently revised.

[179] *See* Form PF Frequently Asked Question A.11, Form PF Frequently Asked Questions, *supra* footnote 162.

• Advisers will be required to indicate whether beneficial owners that are broker-dealers, insurance companies, non-profits, pension plans, banking or thrift institutions are U.S. persons or non-U.S. persons.[180] This amendment will allow the Commissions and FSOC to conduct more targeted analysis about risks presented in the United States separate from risks presented abroad. With regard to pension plans, in particular, it is currently unclear whether advisers must report assets in non-U.S. pension plans as governmental pension plans or foreign official institutions. Therefore, this amendment also is designed to improve data quality, based on our experience with the form.

• Advisers will be required to indicate whether beneficial owners that are private funds are either internal private funds (*i.e.,* managed by the adviser or its related persons) or external private funds. This amendment is designed to help the Commissions and FSOC understand the interconnectedness of private funds to each other, which will aid systemic risk assessment and investor protection efforts. Furthermore, this information will help the Commissions and FSOC understand a reporting fund's risk from investor demands for liquidity, because beneficial owners that are external private funds may have less predictable withdrawals than internal private funds.

• We are specifying that ''state'' investors are U.S. state investors to improve data quality and reduce potential confusion.[181]

The amendments provide that if advisers report information in the ''other'' category, they must describe in Question 4 the type of investor, why it would not qualify for any of the other categories, and any other information to explain the selection of ''other.'' This amendment is designed to improve data quality by providing context to the adviser's selection of the ''other'' category and help ensure that advisers do not inadvertently report information in the wrong category.

One commenter stated that more granular reporting on beneficial ownership would support FSOC's analysis of potential sources of systemic risk.[182] This commenter supported requiring additional disclosure of beneficial ownership and recommended requiring additional disclosures of any politically exposed persons and, for each private fund, the percentage of fund investors and fund equity that originated from certain countries. Another commenter recommended allowing advisers to report beneficial ownership on good faith estimates based on the data that they have from investors and stated that the Commissions had not provided a reasonable justification for requiring the proposed, more granular information.[183] We understand from this commenter that advisers may not have information for all beneficial owners of a reporting fund by country and that it may be burdensome to obtain this information.

Country-level information on a fund's beneficial owners is not required to be reported on Form ADV. As proposed, we are thus not requiring reporting of this information on Form PF. We continue to believe that requiring reporting on percentage of the reporting fund's beneficial ownership that is held by U.S. and non-U.S. persons will improve data quality, based on our experience with the form, and will allow for more effective systemic risk analysis. For example, this information will increase the usefulness of the FRB's Financial Accounts, a tool that is used for evaluating trends in and risks to the U.S. financial system.[184] If an adviser is unable to determine the required beneficial ownership data, the amendments specify that an adviser may provide additional explanatory information in its response to Question 4.

Fund Performance. We are adopting several amendments, with modifications, regarding fund performance reporting in current Question 17, which we have redesignated as Question 23.[185] We are adopting, as proposed, amendments to require all advisers to provide gross and net fund performance as reported to current and prospective investors, counterparties, or otherwise for specified fiscal periods using the table in redesignated Question 23 with added instructions specifying which lines to complete depending on whether the adviser is submitting an initial filing, annual update, or quarterly update.[186] These amendments will improve data quality by specifying which fields an adviser should use to report fund performance for the specified filing period.

As discussed further below, the amendments will require an adviser to report its performance as a money-weighted internal rate of return (instead of a time-weighted return), if the reporting fund's performance is reported to investors, counterparties or otherwise as an internal rate of return since inception. This results from a modification from the proposal in which we added an instruction to proposed Question 23 to specify that the reporting fund may report performance as either a time-weighted return or an internal rate of return, but the methodology used for reporting performance should be consistent over time.

In an additional modification from the proposal that is similarly intended to promote data quality through reporting comparability, we are amending the instructions to the table to specify that gross and net performance should be reported using the reporting fund's base currency. This instruction is implicit in the current form, which requires that performance data be provided as reported to investors or as calculated for other purposes, and we are amending the instruction to make it explicit. Accordingly, pursuant to this modification to the proposed instructions, for example, if a reporting fund uses Japanese yen as its base currency, the fund should report its performance using its base currency,

[180] We understand that, in some cases, an adviser may not be able to determine what type of non-U.S. entity the investor is. Current Question 16 provides a category that addressed that scenario in certain circumstances, and we are maintaining this approach. If investors that are not United States persons and about which certain beneficial ownership information is not known and cannot reasonably be obtained because the beneficial interest is held through a chain involving one or more third-party intermediaries, advisers currently report this in current Question 16(m), which we redesignated as Question 22(s).

[181] As proposed, we are also including instructions to Question 22, as well as Question 21, which is current Question 15 (concerning a certain percentage of beneficial ownership), providing that if the reporting fund is the master fund in a master-feeder arrangement, advisers must look through any disregarded feeder fund (*i.e.,* a feeder fund that is not required to be separately reported). This amendment is designed to implement the adopted master-feeder reporting requirements. *See* section II.A.1 (Reporting Master-Feeder Arrangements and Parallel Fund Structures) of this Release.

[182] Fact Coalition Comment Letter.

[183] MFA Comment Letter II.

[184] *See* Financial Accounts of the United States, *available at http://www.federalreserve.gov/releases/z1/.*

[185] In a separate release, the SEC adopted a new rule under the Advisers Act to require advisers to provide certain fund performance information to its private funds' investors in quarterly statements. *See* Private Fund Advisers; Documentation of Registered Investment Adviser Compliance Reviews, Advisers Act Release No. IA–6383 (Aug. 23, 2023) [88 FR 63206 (Sept. 14, 2023)] (''SEC Private Fund Advisers Adopting Release'').

[186] As proposed, we also are reorganizing the table so monthly, quarterly, and yearly data is presented in separate categories, but this change will not affect reporting frequency; advisers will continue to report information according to the same intervals. We are also amending the table to refer to the end date of each applicable month, quarter, and year, rather than last day of the fiscal period, to reflect the amendments to the reporting period, as discussed above. *See supra* section II.A.3 (Reporting Timelines) of this Release, and Question 23(a).

which is Japanese yen. We also are adopting, as proposed, amendments to require advisers to identify the currency in Question 4.[187] This amendment is designed to inform the Commissions and FSOC of the currency the adviser used to report the reporting fund's gross and net performance, for more accurate and informed analysis.

One commenter stated the proposed requirement does not specify whether net performance should be net of all fund fees and expenses or net of only management fees, incentive fees and allocations, which are referenced in the column header for net performance in Question 23(a); and that it is relatedly unclear whether gross performance should reflect the deduction of all other fund fees and expenses.[188] This commenter suggested that such a result would be inconsistent with the treatment of gross performance in the SEC investment adviser marketing and the private fund adviser rules, which do not require that gross performance reflect the deduction of any fees or expenses. This commenter also stated that the Global Investment Performance Standards require that gross returns reflect the deduction of only transaction costs and that the deduction of any additional fees and expenses is optional. For purposes of Form PF, advisers must provide the net performance and gross performance information that they provide to investors, counterparties, or otherwise (or the most representative set of performance information if the adviser reports different fund performance results to different groups, with an explanation of its selection to be provided in Question 4). Consistent with the reference to management fees, incentive fees, and allocations in the column header for net performance in Question 23(a), net performance should always reflect the deduction of adviser compensation. In addition, Form PF provides confidential reporting to the Commissions, rather than reporting of performance information to current investors. Given these different purposes and audiences for the information, it is not necessary for us to further specify how to calculate gross performance or net performance for purposes of Form PF. These amendments are designed to allow the Commissions and FSOC to compare performance volatility to identify market trends for systemic risk analysis and investor protection efforts.

We are also adopting, as proposed, amendments to create an alternative to the gross and net performance tabular reporting. If the reporting fund's performance is reported to current and prospective investors, counterparties, or otherwise as an internal rate of return since inception, the adviser will be required to report its performance as an internal rate of return.[189] If such information is reported to current and prospective investors, counterparties, or otherwise, in a currency other than U.S. dollars, advisers will be required to report the data using that currency, and identify the currency in Question 4.[190] This approach is designed to acknowledge that advisers calculate performance data differently for different types of private funds. For example, advisers of private equity funds may use a money-weighted rate of return, such as an internal rate of return, to calculate performance data, while advisers to liquidity funds and hedge funds may use a time-weighted rate of return. These calculations may differ in the way they reflect the impact of the timing of external cash flows, among other things. Therefore, the adopted change will allow the Commissions and FSOC to improve the usefulness and quality of performance data to conduct more accurate analysis, including comparisons, and aggregations.

One commenter noted that proposed Questions 23(a) (gross and net performance) and 23(b) (internal rate of return) may be mutually exclusive for some reporting funds.[191] This commenter recommended allowing either Question 23(a) or Question 23(b) to be left blank, as appropriate. We do not believe such a specification is necessary because the instructions provide that an adviser should respond to either Question 23(a) or 23(b), as applicable, and it is generally understood that an adviser may leave blank any inapplicable question.

The instructions to Question 23 provide that an adviser may report the reporting fund's performance either as a time-weighted return or a money-weighted return, such as an internal rate of return.[192] We are adopting defined terms for ''rate of return'' and ''internal rate of return'' in the Form PF Glossary of Terms. In a modification from the proposal, ''rate of return'' is generally defined as the percentage change in the reporting fund's net asset value (or, when a net asset value is not available, in the reporting fund aggregate calculated value) in the reporting fund's base currency from one date to another and adjusted for subscriptions and redemptions.[193] Further, in a modification from the proposal, the rate of return for a portfolio position is defined as the percentage change in the position calculated value, adjusted for income earned and for changes in the quantity held resulting from activity, such as purchases, sales, or splits.[194] As proposed, ''internal rate of return'' is defined as the discount rate that causes the net present value of all cash flows throughout the life of the fund to be equal to zero. One commenter supported the proposed ''internal rate of return'' definition and recommended clarifying how the terms reporting fund aggregate calculated value and currency, which are referenced in the ''rate of return'' definition, apply to the ''internal rate of return'' definition.[195] ''Internal rate of return'' and ''rate of return'' are distinct defined terms in the Form PF Glossary of Terms, and reporting fund aggregate calculated value and currency are not referenced in and do not apply to the definition of ''internal rate of return.'' [196] Further, reporting fund aggregate calculated value is only used when a net asset

[187] *See* Question 23(a).

[188] Comment Letter of CFA Institute (Oct. 11, 2022) (''CFA Institute Comment Letter'').

[189] *See* instructions to Question 23 and Question 23(b). Question 23(b) also requires that if the fund reports different performance results to different groups, advisers must provide the most representative results and explain their selection in Question 4. The instructions to Question 23(b) specify that internal rates of return for periods longer than one year must be annualized, while internal rates of return for periods one year or less must not be annualized. This instruction is designed to help ensure consistent reporting for accurate comparisons.

[190] *See supra* in this section II.A.2 of the Release for further discussion of this amendment.

[191] AIMA/ACC Comment Letter.

[192] *See* Question 23. The instructions provide that the methodology used for reporting performance (*i.e.,* as a time-weighted return or money-weighted return, such as an internal rate of return) should be consistent over time.

[193] The proposed definition of ''rate of return'' was generally the percentage change in the reporting fund aggregate market value in the reporting fund's base currency from one date to another and adjusted for subscriptions and redemptions. The modified definition we are adopting includes reference to a change in the fund's net asset value and modifies the reference to reporting fund aggregate market value to use the defined term in Form PF, reporting fund aggregate calculated value.

[194] The proposed definition generally was that the rate of return for a portfolio position is the percentage change in the position market value, adjusted for income earned. One commenter recommended that we modify this definition stating that a position return cannot be calculated by considering only changes in a portfolio's position value adjusted for income and should also consider changes in quantity resulting from transactions. *See* CFA Institute Comment Letter. After considering comments, we have changed the reference to ''position market value'' in the adopted definition to refer instead to the defined term in Form PF, ''position *calculated* value,'' and we have added reference to adjustments for changes in quantity resulting from activity such as purchases, sales, or splits.

[195] *See* CFA Institute Comment Letter.

[196] *See* Form PF Glossary of Terms (definitions of ''internal rate of return'' and ''rate of return'').

value is not available for calculation of a rate of return. In a modification from the proposal, we are adding an instruction to Questions 23(a) and 23(b) to specify that the reporting fund's performance should not be calculated using a reporting fund aggregate calculated value because this question is intended to report performance, as reported to investors. One commenter recommended requiring funds to consistently report the same type of returns over time and not switch between a rate of return calculation, which is time weighted, and an internal rate of return, which is money weighted.[197] We agree with this commenter and believe that consistent reporting of returns is important for data comparability. Therefore, in a change from the proposal, Question 23 includes an instruction that the methodology used to report performance should remain consistent over time. One commenter stated the proposed definition does not specify whether to include the impact of subscription facilities [198] in the internal rate of return calculation and requested that we specify whether returns should be reported with or without the impact of any subscription facilities.[199] In a change from the proposal, we are requiring advisers in responding to Question 23 to indicate whether the reported internal rate of return includes or does not include the impact of subscription facilities to allow for improved data comparability. It is necessary for an adviser to specify whether the reported rate of return includes or excludes the impact of subscription facilities to be able to accurately compare data between reporting periods. For example, an adviser that reports an internal rate of return with the impact of fund-level subscription facilities in one reporting period but reported without the impact of subscription facilities in a prior period could report artificially increased performance metrics.

We are also adopting amendments, as proposed except as indicated below, that require advisers to report additional performance-related information if the adviser calculates a market value on a daily basis for any position in the reporting fund's portfolio. In such a case, the adviser will be required to report several items. First, it would report the ''reporting fund aggregate calculated value'' at the end of the reporting period.[200] Advisers that file a quarterly update also will report the reporting fund aggregate calculated value as of the end of the first and second month of the reporting period.[201] Second, the adviser will report the reporting fund's volatility of the natural log of the daily ''rate of return'' for each month of the reporting period, following a prescribed methodology.[202] Advisers will be required to report whether the reporting fund uses a different methodology than is prescribed in Form PF to report to current and prospective investors, counterparties, or otherwise, and if so, describe it in Question 4.[203] One commenter recommended requiring volatility measurements over longer periods, such as quarterly or annually, stating that requiring daily measurements would result in a smaller population size and less meaningful information.[204] We believe receiving reporting on the volatility of daily returns on a monthly basis is important because significant volatility swings that occur over a short timeframe may not be discernible from quarterly or annual data but can pose systemic risk. Further, receiving higher frequency volatility data will give more context to a fund's reported monthly returns and will allow us to assess risk-adjusted returns. We understand that it is common practice for advisers to annualize volatility calculations and compare across different time intervals.[205]

Third, the adviser must report whether the reporting fund had one or more days with a negative daily rate of return during the reporting period. If so, advisers will be required to report (1) the most recent peak to trough drawdown, and indicate whether the drawdown was continuing on the data reporting date, (2) the largest peak to trough drawdown, (3) the largest single day drawdown, and (4) the number of days with a negative daily rate of return in the reporting period.[206] These measures are designed to help us and FSOC understand risk, particularly in reporting funds with unique return patterns that are poorly measured using volatility alone. We understand that advisers use drawdown metrics, therefore, this question also is designed to be more reflective of industry practice, and in turn improve data quality.

Advisers are required to report these figures as an amount in the fund's base currency and, in a modification from the proposal, as a percentage in the fund's base currency. One commenter recommended changing amount in base currency to percent in base currency.[207] We agree with requiring reporting of percent in base currency to improve data comparability, and we do not believe requiring percent in addition to amount is incrementally more burdensome to report because the adviser can leverage existing reporting of the amount in base currency and NAV to provide this metric. Requiring an adviser to also report the percent in base currency will improve data comparability because it will provide consistency across data reported by the adviser, rather than potentially using a different exchange rate than the adviser used. This commenter also recommended providing definitions and examples of how to calculate the most recent and largest peak-to-trough drawdown and provided a recommended definition. We do not believe it is necessary to specify a particular methodology to calculate these metrics, which we understand advisers commonly calculate for their funds. Together, the adopted changes are designed to allow the Commissions and FSOC to compare volatility more accurately across different fund types to identify market trends (*e.g.,* volatility of a specific fund type), for systemic risk assessment and investor protection efforts. For example, if several reporting

[197] *See* CFA Institute Comment Letter.

[198] Subscription facilities (or subscription lines) generally refer to credit lines that are guaranteed by committed but uncalled capital.

[199] *See* CFA Institute Comment Letter.

[200] The amendments to Form PF adopted in the May 2023 SEC Form PF Amending Release, *supra* footnote 4, added a definition for ''reporting fund aggregate calculated value.'' *See* Form PF Glossary of Terms. *See also* Question 23(c). We have modified the reference in the proposed Question to ''reporting fund aggregate market value'' to the defined term in Form PF, the reporting fund aggregate *calculated* value.

[201] *See* Question 23(c)(i).

[202] *See* discussion of definitions of ''rate of return'' and ''position market value,'' *supra* footnotes 193 and 194. The prescribed methodology is the standard deviation of the natural log of one plus each of the daily rates of return in the month, annualized by the square root of 252 trading days. When calculating the natural log of a daily rate of return, the rate of return, which is expressed as a percent, must first be converted to a decimal value and then one must be added to the decimal value. *See* Form PF Glossary of Terms and Question 23(c)(ii). Although the reference to ''of one plus each'' was in the proposing release, it was inadvertently left out of the proposed form. We are revising the form to include this language. To reduce potential confusion, we are also specifying in the instruction to this question that, when calculating the natural log of a daily rate-of-return, the rate of return, which is expressed as a percent, must first be converted to a decimal value and then one must be added to the decimal value.

[203] *See* Question 23(c)(iii).

[204] CFA Institute Comment Letter.

[205] We have also modified the table in Question 23(c)(ii) to refer to ''annualized'' volatility of returns, rather than monthly, as proposed, to correspond with the instructions which require the adviser to report the volatility data for each month of the reporting period, on an annualized basis.

[206] *See* Question 23(c)(iv).

[207] CFA Institute Comment Letter.

funds that engage in similar trading activity experience a surge in volatility, the volatility itself or the reporting funds' response to the volatility may impact others who also are engaging in similar trading activity, which could pose systemic risk, and negatively affect investors.

3. Amendments to Section 1c of Form PF—Concerning All Hedge Funds

Section 1c requires advisers to report information about the hedge funds they advise. We are adopting, as proposed except as specified below, amendments to require advisers to report additional information about hedge funds to provide greater insight into hedge funds' operations and strategies, assist in identifying trends, and improve data quality and data comparability for purposes of systemic risk assessments and to further investor protection efforts. We are also removing certain questions where other questions provide the same or more useful data to streamline reporting and reduce reporting burdens without compromising investor protection efforts and systemic risk analysis.

Investment Strategies. We are adopting, as proposed except as specified below, amendments to how advisers report hedge fund investment strategies.[208] We are adopting, as proposed, amendments to require advisers to indicate which investment strategies best describe the reporting fund's strategies on the last day of the reporting period, rather than allowing advisers flexibility to report information as of the data reporting date or throughout the reporting period, as Form PF currently provides.[209] This amendment is designed to improve data quality by specifying how to report information if the reporting fund changes strategies over time. Relatedly, in a modification from the proposal, we are also including an instruction that specifies the methodology an adviser uses for selecting reporting strategies should be consistent over time. This instruction is designed to improve data quality and comparability by specifying that an investment strategy should be categorized consistently from one reporting period to the next. This instruction will also simplify the categorization process for an adviser because it will require an adviser to only determine once how to categorize an ongoing investment strategy.

We also are adopting, as proposed except as specified below, amendments to update the strategy categories that advisers can select to reflect our understanding of hedge fund strategies better and to improve data quality and comparability, based on experience with the form. For example, we are including more granular categories for equity strategies, such as factor driven, statistical arbitrage, and emerging markets. Similarly, we are including more granular categories for credit strategies, such as litigation finance, emerging markets, and asset-backed/structured products. These more granular categories are designed to allow the Commissions and FSOC to conduct more targeted analysis and improve comparability among advisers and hedge funds, which the Commissions and FSOC can use to identify and address systemic risk and investor protection issues in times of stress more accurately. In a modification from the proposal, to facilitate completion of this question and alleviate challenges filers face in choosing among a limited list of investment strategy types, filers will be able to choose from a ''drop-down'' menu that includes all investment strategy categories for Form PF.[210]

We also are adding, as proposed, categories that have become more commonly pursued by hedge funds since Form PF was adopted, such as categories concerning real estate and digital assets.[211] Currently, advisers may report information regarding these strategies in the ''other'' category, resulting in less robust Form PF data for analysis, especially when such analysis filters results based on strategy.[212] The additional categories are designed to improve reporting quality and data comparability across advisers, based on our experience with the form. If an adviser selects the ''other'' category, the adviser will be required to describe in Question 4 the investment strategy, why the reporting fund would not qualify for any of the other categories, and any other information to explain the selection of ''other.'' The requirement to provide an explanation in Question 4 is designed to improve data quality by providing additional context to the adviser's selection of the ''other'' category and will improve our understanding of the adviser's strategies, which may present systemic risk. It also is designed to help us ensure that advisers are not misreporting information in the ''other'' category when they should be reporting information in a different category.

In addition to the investment strategy category additions described above that we are adopting as proposed, in a modification from the proposal, we are adopting certain additional strategy categories. We are adopting certain additional strategy categories that are currently included in the available categories in Question 66, which is structured similarly to Question 25 and is used to collect information about private equity fund investment strategies.[213] To facilitate completion of Question 25 and alleviate challenges filers may face in choosing among a limited list of investment strategy types, in a modification from the proposal, filers will be able to choose from a drop-down menu that includes all investment strategy categories for Form PF. The inclusion of these additional categories recognizes that funds classified as hedge funds on Form PF may pursue

[208] We are amending current Question 20 and redesignating it as Question 25.

[209] *See* current Question 20.

[210] For purposes of this question, investment strategies generally include equity (and associated sub-strategies such as long/short market neutral, long only, long/short short bias, and long/short long bias), macro (and associated sub-strategies such as active trading, commodity, currency, and global macro), convertible arbitrage, relative value (and associated strategies such as fixed income asset backed, fixed income convertible arbitrage, fixed income corporate, fixed income sovereign, fixed income arbitrage, and volatility arbitrage), event driven (and associated sub-sub-strategies such as distressed, distressed/restructuring, risk arbitrage/merger arbitrage, equity special situations, and special situations), credit (and associated sub-strategies such as asset based lending, litigation finance, emerging markets, and asset backed/structured products), managed futures/CTA (and associated sub-strategies such as fundamental, quantitative), investment in other funds, private credit (and associated sub-strategies such as direct lending/mid-market lending, distressed debt, junior/subordinate debt, mezzanine financing, senior debt, senior subordinated debt, special situations, venture debt, and other), private equity (and associated sub-strategies such as early stage, expansion/late stage, buyout, distressed, growth, private investment in private equity, secondaries, and turnaround), real estate, real estate investment trusts, real assets excluding real estate, annuity and life insurance policies, litigation finance, digital assets, general partner stakes investing, cash and cash equivalents, and other.

[211] For example, aggregate qualifying hedge fund gross notional exposure to physical real estate has grown by 47% from the second quarter 2021 through the first quarter 2023, to $191 billion. *See* Private Funds Statistics, *supra* footnote 5.

[212] The amount of hedge fund exposure that advisers attribute to the ''other'' category has grown by 30% to $114 billion, from the second quarter 2021 through the first quarter 2023. *See* Private Funds Statistics, *supra* footnote 5.

[213] The additional strategy categories are private credit (and associated sub-strategies such as direct lending/mid-market lending, distressed debt, junior/subordinate debt, mezzanine financing, senior debt, senior subordinated debt, special situations, venture debt, and other), private equity (and associated sub-strategies such as early stage, expansion/late stage, buyout, distressed, growth, private investment in private equity, secondaries, and turnaround), annuity and life insurance policies, litigation finance, and general partner stakes investing. *See also* May 2023 SEC Form PF Amending Release, *supra* footnote 4, at n. 216. Question 66 was added as a new question in the amendments adopted in the May 2023 SEC Form PF Amending Release.

investment strategies more commonly associated with private equity funds and vice versa. This change will allow advisers to categorize their investment strategies more accurately and will improve data quality by reducing the number of strategies that would otherwise be categorized as ''other.'' For similar reasons, in a modification from the proposal, we are also retaining certain investment strategy categories that are included in the current Form PF, which we had proposed to remove, to provide more granular information and maintain existing data comparability.[214] In addition, we are adopting strategy categories for ''Equity Long/Short Market Neutral,'' ''Equity Long/Short Long Bias,'' and ''Equity Long/Short Short Bias,'' and adding separate categories for ''Equity Long Only'' and ''Credit Long/Short,'' as discussed further below.

One commenter opposed including more granular strategy categories stating that some proposed categories are not clear and may require advisers to make subjective decisions on how to report a fund's strategy that could result in inconsistent reporting.[215] This commenter recommended that the strategy categories be revised to better track industry conventions. The amended strategy categories conform more closely to industry conventions than the current categories and will allow advisers to categorize their strategies more accurately. One commenter opposed the increased granularity in strategy categories, stating they could disclose a fund's proprietary investment information and present data security concerns.[216] The data reported on Form PF, which is filed on a non-public basis, is neither sufficiently detailed nor reported on such a frequent basis as to present risk of misuse or enable reverse engineering of a particular fund's investment strategy. One commenter recommended reverting the category for the ''Equity Long/Short'' strategy from the proposed categories of ''Equity Long Bias'' and ''Equity Short Bias'' because of the burden and potential for misreporting of long/short equity funds or portfolios. In a change from the proposal, as recommended by this commenter, we are amending the proposed categories for ''Equity Long Bias'' and ''Equity Short Bias'' and replacing with ''Equity Long/Short Market Neutral,'' ''Equity Long/Short Long Bias,'' and ''Equity Long/Short Short Bias,'' and adding separate categories for ''Equity Long Only'' and ''Credit Long/Short.'' We believe these additional categories better align the strategy categories with industry conventions and addresses the concern with appropriately reporting the strategy category for long/short equity funds or portfolios.

As proposed, digital assets will be included as a reportable investment strategy.[217] In a change from the proposal, however, we are not adopting a defined term for ''digital assets'' in the Glossary of Terms. Some commenters supported adding a defined term for digital assets and emphasized the growing impact of digital assets on the financial sector more broadly and the systemic risk that they may pose.[218] Other commenters stated that the proposed definition of digital asset is too broad and may overlap with other existing reporting categories.[219] One commenter recommended excluding from the digital asset definition references to any specific types of digital assets because of the evolving terminology used in the sector.[220] Another commenter recommended that the references to digital assets be consistent across usages by the SEC.[221] This commenter also recommended adopting distinct defined terms for different types of digital assets to differentiate between different asset categories that may present different risks, such as differentiating between established digital assets and newer digital assets. Another commenter recommended distinguishing between so-called ''stablecoins'' and other digital assets on the basis that stablecoins may be less volatile than other digital assets.[222]

The Commissions and staff are continuing to consider the issues raised by these comments, and we are not adopting a definition as part of this rule at this time. However, we agree with commenters stating that certain strategies could be categorized as either a digital asset strategy or another listed strategy, and so in those instances the digital asset strategy is duplicative.[223] Accordingly, we are including an instruction to Question 25 to specify that, if a particular strategy could be classified as both a digital asset strategy and another strategy, an adviser should report the strategy as the non-digital asset strategy. This is designed to reduce potential confusion and improve data quality.

Counterparty exposures. Counterparty exposure informs the Commissions and FSOC of the interconnectedness of hedge funds with the broader financial services industry, which is a critical part of systemic risk assessment and investor protection efforts. Understanding counterparty exposures allows the Commissions and FSOC to assess who may be impacted by a reporting fund's failure, and which reporting funds may be impacted by a counterparty's failure. Counterparty exposure concerning central clearing counterparties (''CCPs'') is of importance to FSOC's systemic risk assessment efforts as evidenced by the fact that FSOC has designated many CCP institutions as ''systemically important,'' and recommended that regulators continue to coordinate to evaluate threats from both default and non-default losses associated with CCPs.[224]

We are adopting, as proposed except as indicated below, amendments to add Question 26 and revise current Questions 22 and 23, which have been redesignated as Questions 27 and 28, to provide better insight into hedge funds' borrowing and financing arrangements with counterparties, including CCPs. Question 26 requires advisers to hedge funds (other than qualifying hedge funds) to complete a new table (''consolidated counterparty exposure table'') concerning exposures that (1) the reporting fund has to creditors and

[214] We are retaining the existing investment strategies listed in current Question 20 for the following categories: Macro, Active Trading; Macro, Commodity; Macro, Currency; Relative Value, Fixed Income Asset Backed; Relative Value, Fixed Income Convertible Arbitrage; Relative Value, Fixed Income Sovereign; Event Driven, Distressed/Restructuring; Event Driven, Equity Special Situations; and Credit, Long/Short. *See* Question 25.

[215] MFA Comment Letter II.

[216] SIFMA Comment Letter.

[217] As discussed further below in section II.C.2 of this Release, we are also adopting amendments to Question 32 to add digital assets as a reportable sub-asset class.

[218] *See, e.g.,* Better Markets Comment Letter; NASAA Comment Letter.

[219] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; USCC Comment Letter.

[220] Comment Letter of Rohan G. et al. (Dec. 8, 2022) (''Rohan G. Comment Letter'').

[221] NASAA Comment Letter.

[222] AFREF Comment Letter I.

[223] For example, a crypto asset security is not a separate type or category of security for purposes of Federal securities laws based solely on the use of distributed ledger technology. *See* Supplemental Information and Reopening of Comment Period for Amendments Regarding the Definition of ''Exchange,'' 88 FR 29448, 29450 (May 5, 2023) (stating ''a crypto asset that is a security is not a separate type or category of security (*e.g.,* NMS stock, corporate bond) for purposes of federal securities laws based solely on the use of DLT.'').

[224] Form PF defines ''CCP'' as central clearing counterparties (or central clearing houses) (for example, CME Clearing, The Depository Trust & Clearing Corporation, Fedwire and LCH Clearnet Limited). *See* Financial Stability Oversight Council, 2012 Annual Report, Appendix A, *available at https://home.treasury.gov/system/files/261/2012-Annual-Report.pdf* (concerning the designations); Financial Stability Oversight Council, 2021 Annual Report, p. 14, *available at https://home.treasury.gov/system/files/261/FSOC2021AnnualReport.pdf* (concerning the recommendation).

counterparties, and (2) creditors and other counterparties have to the reporting fund.[225] Advisers will be required to report the U.S. dollar value of the reporting fund's ''borrowing and collateral received (B/CR),'' as well as its ''lending and posted collateral (L/PC),'' aggregated across all counterparties, including CCPs, as of the end of the reporting period.[226] The form explains what exposures to net.[227] Advisers will be required to classify information according to type (*e.g.,* unsecured borrowing, secured borrowing, derivatives cleared by a CCP, and uncleared derivatives) and the governing legal agreement (*e.g.,* a prime brokerage or other brokerage agreement for cash margin and securities lending and borrowing, a global master repurchase agreement for repo/reverse repo, and International Swaps and Derivatives Association (''ISDA'') master agreement for synthetic long positions, ''synthetic short positions,'' and derivatives).[228] Advisers will be required to report transactions under a master securities loan agreement as secured borrowings. Advisers will be required to check a box if one or more prime brokerage agreements provide for cross-margining of derivatives and secured financing transactions. If advisers check the box, the instructions specify how to report secured financing and derivatives in the consolidated counterparty exposure table.

Some commenters opposed more granular disclosure of counterparty exposures, stating that the information is burdensome to obtain and of limited value.[229] One commenter stated that reporting on exposures to central clearing counterparties should be on an aggregate basis, rather than on an individual basis, because of the cost to report and limited value of the disaggregated data.[230] We continue to believe that this additional information is important to understanding counterparty risk exposure, which is needed for systemic risk assessment because of the potential contagion risks of any particular counterparty failure, and that the value of this information justifies the associated burdens in reporting.[231] We believe that the associated burdens are justified because detailed reporting of counterparty risk exposure will provide the Commissions and FSOC with increased transparency into risk profiles and the interconnectedness of hedge funds with the broader financial services industry, which will improve our ability to assess systemic risk and protect investors.

We are adopting, largely as proposed, several amendments to Questions 26, 27 and 28, which require advisers to hedge funds to provide information about the reporting fund's counterparty exposure, as follows:

- We are adopting, as proposed except as specifically indicated below, amendments to Questions 27 and 28 to provide more detailed instructions for advisers to use to identify the individual counterparties. For both Questions 27 and 28, advisers are instructed to use the calculations from the consolidated counterparty exposure table to identify the counterparties.[232] This amendment is designed to help ensure that the Commissions' and FSOC's analysis can identify true data differences, without the distraction of methodology differences, which can suggest differences where there are none, and reduce circumstances where advisers misidentify lending relationships. In a modification from the proposal, we are adding an instruction to specify the entity that has the reported exposure.[233] This modification will allow us to determine the relevant entity that bears such exposure (*e.g.,* a trading vehicle), which will improve our data quality and our ability to monitor systemic risk.[234] The amended instructions provide that if the entity that has the exposure is not the reporting fund, the filer must provide the legal name of the relevant entity and LEI, if available.[235] This instruction will allow us to better understand the scope of the reporting fund's exposure.[236] We did not receive specific comment on these amendments to the instructions. These amendments will improve data quality and comparability and reduce adviser burden.
- We are adopting, as proposed, amendments to add Question 27, which requires advisers to identify each creditor or other counterparty (including CCPs) to which the reporting fund owes a certain amount (before posted collateral) equal to or greater than either (1) five percent of net asset value as of the data reporting date or (2) $1 billion. If there are more than five such counterparties, the adviser only will report the five counterparties to which the reporting fund owes the largest dollar amount, before taking into account collateral that the reporting fund posted. If there are fewer than five such counterparties, the adviser only will report the counterparties that meet the threshold. For example, if only three

[225] Qualifying hedge funds are not required to complete this table because section 2, as revised, includes similar questions that require additional detail. *See* discussion at section II.C of this Release. Together the questions in section 1c and similar questions at section 2 will allow the Commissions and FSOC to consolidate information relating to hedge funds' and qualifying hedge funds' arrangements with creditors and other counterparties, to support systemic risk assessment and investor protection efforts. We are defining the term ''consolidated counterparty exposure table'' in the Form PF Glossary of Terms. For hedge funds other than qualifying hedge funds, it means the section 1c table (at Question 26) that collects the reporting fund's borrowing and collateral received and lending and posted collateral aggregated across all creditors and counterparties as of the end of the reporting period. For qualifying hedge funds, it means the section 2 table (at Question 41) that collects the reporting fund's borrowing and collateral received and lending and posted collateral aggregated across all creditors and counterparties as of the end of the reporting period.

[226] We are defining ''borrowing and collateral received (B/CR)'' and ''lending and posted collateral (L/PC)'' in the Form PF Glossary of Terms. We are adopting these definitions based on our understanding of borrowing and lending and to help ensure data quality and comparability. We also are amending the term ''gross notional value'' to provide more detail on how to report it to aid advisers completing the consolidated counterparty exposure table. *See* Form PF Glossary of Terms.

[227] Advisers will net the reporting fund's exposure with each counterparty and among affiliated entities of a counterparty to the extent such exposures may be contractually or legally set-off or netted across those entities or one affiliate guarantees or may otherwise be obligated to satisfy the obligations of another under the agreements governing the transactions. Instructions provide that netting must be used to reflect net cash borrowed from or lent to a counterparty but must not be used to offset securities borrowed and lent against one another, when reporting prime brokerage and repo/reverse repo transactions. These instructions are designed to help ensure data quality and comparability. *See* Question 26.

[228] We are adopting, as proposed, a definition of ''ISDA'' as the International Swaps and Derivatives Association. We are also adopting a definition of ''synthetic short positions'' in the Form PF Glossary of Terms (*see* the Form PF Glossary of Terms). We are adopting this definition based on our understanding of the instruments and to help ensure data quality to aid comparability. *See supra* footnote 161 (discussing the definition of ''synthetic long position'').

[229] *See, e.g.,* AIMA/ACC Comment Letter.

[230] MFA Comment Letter II.

[231] S*ee infra* section IV.C of this Release for discussion of costs and benefits.

[232] *See* Question 26 for the consolidated counterparty exposure table. We are also adopting, substantively as proposed, definitions for the following terms related to the consolidated counterparty exposure table: ''cash borrowing entries,'' ''cash lending entries,'' ''collateral posted entries,'' and ''collateral received entries.'' *See* Form PF Glossary of Terms.

[233] *See* Question 27.

[234] As discussed more fully above in section II.A.2, we are adopting amendments to include specific questions relating to a reporting fund's trading vehicle use and a trading vehicle's position size and risk exposure, as opposed to requiring full separate reporting on Form PF for trading vehicles. This modification will allow us to understand which entity holds the exposure.

[235] *See* Question 27.

[236] This modification is related to our modification from the proposal to require aggregated reporting and focusing certain questions on trading vehicles, rather than disaggregated reporting as proposed, discussed above in section II.A.2. This modification to the instructions will allow us to understand whether the reporting fund or a trading vehicle holds the exposure.

counterparties meet the threshold, the adviser would report only three counterparties. This is a change from current Question 22, which required advisers to identify five counterparties to which the reporting fund has the greatest mark-to-market net counterparty credit exposure, regardless of the actual size of the exposure. The adopted threshold is designed to highlight two different, significant, potentially systemic risks: five percent of net asset value represents an amount of borrowing by a reporting fund that, if repayment was required, could be a significant loss of financing that could result in a forced unwind and forced sales from the reporting fund's portfolio. Additionally, the $1 billion represents an amount that, in the case of a very large fund, may not represent five percent of its net assets, but may be large enough to create stress for certain of its counterparties. One commenter recommended that the additional reporting on counterparties should be limited to a fund's three largest counterparties to reduce the burden on advisers but provide the Commissions with sufficiently detailed information on counterparty exposure.[237] We continue to believe that requiring reporting of the five largest counterparties is appropriate and do not believe that limiting the required reporting to a fund's three largest counterparties would provide sufficient counterparty risk data for the purposes discussed above. Furthermore, we do not believe that reporting on a fund's five largest counterparties would be significantly more burdensome than reporting on the three largest counterparties because an adviser could leverage its systems for reporting on the three largest counterparties to provide reporting on the five largest counterparties.

- In a modification from the proposal, advisers will also be required to provide the legal name and the LEI, if any, of the entity that has the exposure. This information will allow us to determine the relevant entity that bears such exposure (*e.g.,* a trading vehicle), which will improve our data quality and our ability to monitor systemic risk.[238]
- In a modification from the proposal, the instructions to Question 26 provide that an adviser is required to report the reporting fund's counterparty exposure without netting any trading vehicle exposures if the reporting fund does not guarantee and is not contractually obligated to fulfill those counterparty obligations.[239] The instructions will further provide that if the reporting fund guarantees or is obligated to fulfill the trading vehicle's counterparty obligations, then those obligations must be reported net with the obligations of the reporting fund. These modified instructions are intended to address the aggregated reporting of trading vehicles and improve data quality by isolating only the reporting fund's counterparty exposures. In a modification from the proposal, the instructions also provide that any affiliated private fund should exclude any exposures that have been reported in the reporting fund's filing. This modified instruction is intended to reduce filing burdens by eliminating duplicate reporting and to improve data quality.
- We are adopting, largely as proposed except as specified below, amendments to add Question 28, which requires advisers to provide information for counterparties to which the reporting fund has net mark-to-market counterparty credit exposure which is equal to or greater than either (1) five percent of the reporting fund's net asset value as of the data reporting date or (2) $1 billion, after taking into account collateral received or posted by the reporting fund. If there are more than five such counterparties, the adviser would only report the five to which the reporting fund has the greatest mark-to-market exposure after taking into account collateral received. If there are fewer than five such counterparties, the adviser only would report the counterparties that meet the threshold. This is a change from current Question 23, which required advisers to identify five counterparties to which the reporting fund has the greatest mark-to-market net counterparty credit exposure, regardless of the actual size of the exposure. The threshold is designed to represent an amount of lending from a reporting fund that, if a default occurred, could cause a significant loss that could result in a forced unwind and forced sales from the reporting fund's portfolio. Furthermore, we believe that the five percent threshold level is large enough to constitute a shock to a reporting fund's net asset value and is an often-used industry metric. The $1 billion threshold represents an amount that, in the case of a very large counterparty, may not represent five percent of its net assets, but may be large enough to create stress for the reporting fund. In a modification from the proposal, we are adding an instruction to specify the entity that has the reported exposure.[240] The amended instructions provide that if the entity that has the exposure is not the reporting fund, the filer must provide the legal name of the relevant entity and LEI, if available. This instruction will allow us to better understand the scope of the reporting fund's exposure. One commenter recommended a threshold of 10 percent of a fund's net asset value, rather than five percent, for all reporting related to exposures, including counterparty exposure, on the basis that 10 percent of net asset value better represents a magnitude that could have broader systemic effects and a five percent threshold would produce data that is not meaningful for risk assessments.[241] We disagree and continue to believe that the impact on a fund's returns resulting from a counterparty exposure of greater than five percent could be significant enough to present systemic risk and contagion risk. Currently, advisers report exposures that the reporting fund has to counterparties as a percentage of the reporting fund's net asset value, and advisers report exposures that counterparties have to the reporting fund in U.S. dollars.[242] We are adopting, as proposed, an amendment that requires advisers to report both data sets in U.S. dollars for consistency and comparability.[243] We did not receive specific comment on this amendment.
- We are adopting, as proposed, an amendment to require advisers to report the amount of collateral posted, to help inform the Commissions and FSOC of the potential impact of a reporting fund or counterparty default. We did not receive specific comment on this amendment.
- We are adopting, as proposed, an amendment to require advisers to report the counterparty's LEI, if it has one, to help identify counterparties and more efficiently link data from other data sources that use this identifier. We did not receive specific comment on this amendment.
- Advisers will continue to indicate if a counterparty is affiliated with a major financial institution, as Form PF currently provides.[244] If the financial institution is not listed on Form PF, advisers would continue to have the option of selecting ''other'' and naming the entity in the chart, as Form PF currently provides. However, we are adopting, as proposed, an amendment to require advisers to describe the financial

[237] MFA Comment Letter II.

[238] *See also supra* section II.A.2 of this Release for further discussion of trading vehicle reporting.

[239] *See* Question 26.

[240] *See* Question 28.

[241] MFA Comment Letter II.

[242] *See* current Questions 22 and 23.

[243] *See* Questions 27 and 28.

[244] *See* current Questions 22 and 23.

institution in Question 4. This amendment is designed to help the Commissions and FSOC efficiently and accurately identify the entity, without having to contact advisers individually. We did not receive specific comment on this amendment.

Together, the amendments are designed to allow the Commissions and FSOC to identify and align sources of borrowing and lending to identify significant counterparty exposures, so that different styles of borrowing will not be obscured by methodology differences or misidentified lending relationships, based on our experience with the form.

Form PF continues to require advisers to report information about individual counterparties that present the greatest exposure to and from hedge funds.[245] Under the amended Form PF, however, advisers to qualifying hedge funds will not be required to complete Questions 27 and 28, if they complete certain similar questions in Form PF section 2, to avoid duplication.[246]

Trading and clearing mechanisms. We are adopting, as proposed, amendments to revise how advisers report information about trading and clearing mechanisms.[247] These types of data inform the Commissions and FSOC of the extent of private fund activities that are conducted on and away from regulated exchanges and clearing systems, which is important to understanding systemic risk that could be transmitted through counterparty exposures.[248] We are adopting amendments to require advisers to report (1) the value traded and (2) the value of positions at the end of the reporting period, rather than requiring advisers to report information as a percentage in terms of value and trade volumes, as Form PF currently requires.[249] This change is designed to simplify reporting because advisers compute the value before they convert it into a percentage; therefore, this change eliminates an extra calculation for advisers. It also is designed to provide the Commissions and FSOC with data that can be more efficiently compared and aggregated among advisers and other data sources. With data in dollar values, the Commissions and FSOC could more effectively estimate the size, extent, and pace of each hedge fund's participation in activity on or away from regulated exchanges and clearing systems in relation to total values. Understanding the size of hedge fund participation in activity on and away from regulated exchanges and clearing systems is important to assessing systemic risk, because activity that takes place on regulated exchanges and clearing systems presents different risks than activity that takes places away from regulated exchange and clearing systems. For example, activity that takes place away from a regulated exchange or clearing system may be less transparent, and may present more credit risk, than activity that takes place on a regulated exchange and a clearing system that acts as a central counterparty that guarantees trades. Commenters generally supported amendments that simplify reporting requirements.[250] This amendment will reduce burdens on advisers by eliminating an additional calculation and will improve data comparability.

We also are adopting amendments to require advisers to report information about trading and clearing mechanisms for transactions in interest rate derivatives separately from other types of derivatives. Form PF data show that interest rate derivatives represent the largest gross investment exposure of qualifying hedge funds.[251] Therefore, this amendment is designed to help ensure that the Commissions and FSOC can identify risks of such a significant volume of activity on and away from regulated exchanges and clearing systems, without the data being obscured by other types of derivatives. Advisers will be required to report interest rate derivatives and other types of derivatives, by indicating the estimated amounts that were (1) traded on a regulated exchange or swap execution facility, (2) traded over-the-counter and cleared by a CCP, and (3) traded over the counter or bilaterally transacted (and not cleared by a CCP). These categories reflect our understanding of how derivatives may be traded.

Advisers continue to be required to report clearing information concerning repos, but we are adopting amendments to specify how to report sponsored repos and to specify that advisers must report reverse repos with repos.[252] According to the Fixed Income Clearing Corporation (''FICC''), FICC's sponsored repo service has expanded in 2017 and 2019, ultimately resulting in daily volume up to $300 million per day as of 2021, with a peak in June 2023 of $750 billion.[253] Sponsored repos incorporate a different structure than other repos, in that FICC serves as a counterparty to any sponsored trade and the sponsored member bears responsibility for meeting the obligations of the sponsored member on all transactions that it submits for clearing. Adding a particular reference to sponsored repos ensures that advisers understand how sponsored repos cleared by a CCP should be reported, *i.e.,* as trades cleared at a CCP.[254] Therefore, we are providing a separate line item for sponsored repos. The amendment is designed to improve data quality concerning repos and sponsored repos to allow the Commissions and FSOC to conduct more accurate and targeted systemic risk assessments and analysis concerning investor protection efforts. We are also adopting amendments to specify that advisers must report reverse repos with repos. Current Question 24 required advisers to report ''repos,'' which some advisers could interpret to include reverse repos, while others could interpret as

[245] *See* Questions 27 and 28.

[246] *See* Questions 42 and 43 in Form PF section 2 and *supra* footnote 225.

[247] *See* current Questions 24 and 25, which we redesignated as Questions 29 and 30.

[248] *See supra* footnote 224 and accompanying text (discussing the role of CCPs); 2011 Form PF Adopting Release, *supra* footnote 4, at n.228, and accompanying text.

[249] Question 29 specifies that ''value traded'' is the total value in U.S. dollars of the reporting fund's transactions in the instrument category and trading mode during the reporting period. Question 29 also specifies that, for derivatives, value traded is the weighted average of the notional amount of aggregate derivatives transactions entered into by the reporting fund during the reporting period, except for the following: (1) for options, advisers would use the delta adjusted notional value, and (2) for interest rate derivatives, advisers would use the ''10-year bond equivalent.'' This measurement is designed to track standard industry convention. We also are adding the term ''10-year bond equivalent'' to the Form PF Glossary of Terms, as discussed in section II.C.2 of this Release. *See infra* footnote 293.

[250] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter.

[251] *See* Private Funds Statistics, *supra* footnote 5.

[252] The amendments also explain that ''repo'' means ''securities in'' transactions and ''reverse repo'' means ''securities out'' transactions. Sponsored repos and sponsored reverse repos apply to transactions in which the reporting fund has been sponsored by a sponsoring member of the Fixed Income Clearing Corporation. We have revised how Form PF explains tri-party repos to help ensure they do not exclude sponsored tri-party repos. Currently, Form PF explains that a tri-party repo applies where repo collateral is held at a custodian (not including a CCP) that acts as a third party agent to both the repo buyer and the repo seller. We are amending Form PF to explain that tri-party repo applies where the repo or reverse repo collateral is executed using collateral management and settlement services of a third party that does not act as a CCP. *See* Form PF Glossary of Terms (amended definitions of ''repo'' and ''reverse repo'') and Question 29 instructions (discussing sponsored repos, sponsored reverse repos, and tri-party repos).

[253] See FICC Sponsored Repo in 2021, by DTCC Connection Staff (Feb. 9, 2021), *available at https://www.dtcc.com/dtcc-connection/articles/2021/february/09/ficc-sponsored-repo-in-2021. See also* DTC: DTCC's FICC Sponsored Service Reaches New Milestone Clearing Over USD$750 Billion in Daily Sponsored Activity (June 14, 2023), *available at https://www.dtcc.com/news/2023/june/14/dtccs-ficc-sponsored-service-reaches-new-milestone.*

[254] Current Question 24.

excluding reverse repos. Therefore, this amendment is designed to improve data quality.[255]

We are also adopting amendments to revise current Question 25, which requires advisers to report the percentage of the reporting fund's net asset value related to transactions not described in current Question 24, which we have redesignated as Question 29. Advisers will be required to report both the value traded and the position value as of the end of the reporting period for transactions not described in Question 29. These amendments are designed to make Question 30 data comparable with data from Question 29, so that together Questions 29 and 30 will provide the Commissions and FSOC with a complete data set of the adviser's trading and clearing mechanisms during the reporting period. We did not receive comments on these proposed amendments.

Removing Certain Questions Concerning Hedge Funds. We are removing, as proposed, current Questions 19 and 21 from the form. Current Question 19 required advisers to hedge funds to report whether the hedge fund has a single primary investment strategy or multiple strategies. Question 25, which requires hedge fund advisers to disclose certain information about each investment strategy, will provide this information, as discussed above in this section II.B.3 of the Release.

We are also removing current Question 21, which required hedge fund advisers to approximate what percentage of the hedge fund's net asset value was managed using high frequency trading strategies. We believe the form's question on portfolio turnover, with the adopted revisions, will better inform our and FSOC's understanding of the extent of trading by large hedge fund advisers and will better show how larger hedge funds interact with the markets and provide trading liquidity.[256]

Commenters generally supported amendments that eliminate questions and streamline reporting requirements.[257] One commenter stated that, by eliminating the collection of duplicative data, FSOC will be better able to assess systemic risk and the Commissions will be better able to protect investors.[258] One commenter supported removing current Question 21 regarding the percentage of a hedge fund's net asset value managed using high frequency trading strategies.[259] We believe that removing certain questions concerning hedge funds will reduce the burdens on these advisers and the adoption of new and revised questions elsewhere on Form PF will improve our understanding of hedge fund operations to allow for systemic risk analysis and investor protection efforts.

C. Amendments Concerning Information About Hedge Funds Advised by Large Private Fund Advisers

We are adopting, as proposed except as specifically indicated below, several amendments to section 2, including amendments that remove aggregate reporting currently required in existing section 2a, which we have found to be less meaningful for analysis and more burdensome for advisers to report, while preserving and enhancing reporting on a per fund basis in existing section 2b, which we are redesignating as section 2. We are also retaining certain questions currently reported by advisers on an aggregate basis that are important for data analysis and systemic risk assessment but are requiring reporting on a per fund basis. Collectively, the changes to section 2 are designed to provide better insight into the operations and strategies employed by qualifying hedge funds and their advisers and improve data quality and comparability to enable FSOC to monitor systemic risk better and enhance the Commissions' regulatory programs and investor protection efforts. Furthermore, we are also removing certain other reporting requirements that we have found to be less useful based on our experience with Form PF since adoption, which will help reduce reporting burdens for advisers while preserving the Commissions' and FSOC's regulatory oversight.

1. Removal of Existing Section 2a

Removal of aggregate reporting. We are adopting, as proposed, amendments to eliminate the current requirement for large hedge fund advisers to report certain aggregated information about the hedge funds they manage.[260] Based on our experience using data obtained from Form PF since its adoption, we have found that aggregated adviser level information combines funds with different strategies and activities, thus making analyses less meaningful. Aggregation can mask the directional exposures of individual funds (*e.g.,* positions held by one reporting fund may appear to be offset by positions held in a different fund). Additionally, there can be inconsistencies between data currently reported in the aggregate in existing section 2a and on a per fund basis in existing section 2b (*e.g.,* we have observed in some instances that the sum of fund exposures advisers report in current Question 30 on a per fund basis exceeds the aggregate figure reported in current Question 26). Aggregating information across funds may be burdensome for some advisers because certain advisers may keep fund records on different systems and ''rolling-up'' the data from different sources to report on the form may be complex and time consuming. While advisers may be required to aggregate certain types of investment holdings across their funds for other regulatory purposes (*e.g.,* certain U.S. registered equities for Form 13F reporting), advisers generally do not aggregate all portfolio investment exposure information across their funds other than for Form PF reporting purposes, given that counterparties, markets, and investors tend to interact with funds on an individual basis and not in the aggregate at the adviser level.

Commenters generally supported proposed amendments to eliminate questions and streamline reporting requirements.[261] One commenter stated that the aggregate reporting of certain positions may make it difficult to understand the operations of hedge funds, especially during periods of market instability.[262] Another commenter stated that reporting on an aggregate basis does not result in obscuring material data.[263]

We continue to believe that eliminating aggregate reporting questions for large hedge fund advisers will lessen the burden on these advisers and focus Form PF reporting on more valuable information for systemic risk assessment purposes. Removing existing

[255] *See* Question 29.

[256] *See* revisions to current Question 27 (redesignated as Question 34), as discussed in section II.C of this Release.

[257] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter.

[258] Better Markets Comment Letter.

[259] MFA Comment Letter II.

[260] We are removing existing section 2a and redesignating existing section 2b as section 2. In connection with the removal of section 2a, we are revising the general instructions to make corresponding changes (including amending Instruction 3 to reflect the removal of section 2a), and are revising current Question 27 (reporting on the value of turnover in certain asset classes in advisers' hedge funds' portfolios) and current Question 28 (reporting on the geographical breakdown of investments held by advisers' hedge funds), moving each of these questions to new section 2, and redesignating them as Question 34 and Question 35, respectively. Furthermore, in connection with these changes, we are revising the term ''sub-asset class'' to refer to Question 32, rather than current Question 26, which we have removed.

[261] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter.

[262] *See* Better Markets Comment Letter.

[263] *See* AIC Comment Letter I.

section 2a will not result in a meaningful deterioration in the information collected because the vast majority of gross hedge fund assets on which advisers currently report in the aggregate in section 2a constitute the gross assets of qualifying hedge funds that will continue to be reported elsewhere in amended section 2. For example, large hedge fund advisers currently report total gross notional exposure for qualifying hedge funds in section 2b that constituted approximately 91 percent of the total gross notional exposure reported on an aggregate basis by large hedge fund advisers currently in section 2a as of the same date.[264] Furthermore, as discussed in section II.B.3 above, we are also adopting amendments to enhance reporting for all hedge funds in section 1 (particularly section 1c), which will mitigate against potential data gaps that could result from the removal of section 2a, given that advisers currently report information on all their hedge funds in section 2a but only report on qualifying hedge funds in section 2b. Additionally, certain information currently collected in section 2a is duplicative of information that will continue to be collected on a per fund basis in the consolidated section 2.[265] By continuing to require reporting on a per fund basis, information reported elsewhere in the revised section 2 will allow the Commissions and FSOC to compile aggregate figures, as appropriate.[266]

2. Amendments to Section 2

We are redesignating existing section 2b as section 2 and adopting, as proposed except as specified below, amendments to section 2 to do the following:

(1) Enhance, expand, and simplify investment exposure reporting;

(2) Revise open and large position reporting;

(3) Revise borrowing and counterparty exposure reporting;

(4) Revise market factor effects reporting; and

(5) Make certain other changes designed to streamline and enhance the value of data collected on qualifying hedge funds by: (a) adding reporting on currency exposure, turnover, country, and industry exposure; (b) adding new reporting on CCPs; (c) streamlining risk metric reporting and collecting new information on investment performance by strategy; and (d) enhancing portfolio and financing liquidity reporting.

a. Investment Exposure Reporting

We are adopting, largely as proposed except as specified below, amendments to: (1) replace the table format of current Question 30, which we are redesignating as Question 32, with narrative instructions and a ''drop-down'' menu while also revising the instructions to specify how to report certain positions, (2) require reporting based on ''instrument type'' within sub-asset classes to identify whether the fund's investment exposure is achieved through cash or physical investment exposure, through derivatives or other synthetic positions, or indirectly (*e.g.,* through a pooled investment such as an ETF, an investment company, or a private fund), (3) require the calculation of ''adjusted exposure'' for each sub-asset class (*i.e.,* require (in addition to value as currently reported) the calculation of ''adjusted exposure'' for each sub-asset class that allows netting across instrument types representing the same reference asset within each sub-asset class, and, for fixed income, within a prescribed set of maturity buckets), (4) require uniform interest rate risk measure reporting for sub-asset classes that have interest rate risk (while eliminating the current option to report one of duration, weighted average tenor (WAT), or 10-year equivalents), and (5) amend the list of reportable sub-asset classes consistent with these other changes and collect enhanced information for some asset types.[267]

Narrative reporting instructions and additional information on how to report.

We are adopting, as proposed, amendments to the redesignated Question 32 which will require advisers to use a series of ''drop-down'' menu selections for each sub-asset class and the applicable information required for each sub-asset class. These changes and new format will simplify and specify how to report the required information in redesignated Question 32. These changes will reduce filer burdens compared to the current format because advisers will only be required to provide information for sub-asset classes in which their qualifying hedge funds hold relevant positions. Furthermore, advisers will be required to report the absolute value of short positions, include positions held in side-pockets as positions of the reporting fund, and include any closed out and OTC forward positions that have not yet expired or matured. We did not receive comment on these amendments.

We are adopting, as proposed, amendments to the instructions to redesignated Question 32 to specify how advisers should classify certain positions. This change is designed to instruct advisers how to classify positions that could be accurately classified in multiple sub-asset classes and is consistent with SEC staff Form PF Frequently Asked Questions.[268] Specifically, the instructions require advisers to choose the sub-asset class that describes the position with the highest degree of precision, which will result in more accurate classification of positions and therefore better data, rather than simply noting that any particular position should only be included in a single sub-asset class. We did not receive comment on this instruction.

We are also adopting, as proposed, a new instruction that directs advisers to report cash borrowed via reverse repo as the short value of repos and refers advisers to the revised definitions of ''repo'' and ''reverse repo'' in the Glossary of Terms, consistent with SEC staff Form PF Frequently Asked Questions.[269] This change will help reduce confusion on how to report repo information and help reduce filer errors. We did not receive comment on this instruction or the revised definitions. Finally, the amended instructions also include a revised list of sub-asset classes.[270]

We are also adopting, as proposed, amendments to require advisers to

[264] As noted above, based on experience with Form PF since adoption, we have found information currently gathered in section 2a for the remaining 9% of funds to not be very useful given that it is aggregated data across different funds.

[265] For example, current Question 26 of section 2a requires large hedge fund advisers to report aggregated information on exposure to different types of assets, which is effectively the same exposure information that will be reported on a per fund basis for each qualifying hedge fund in Question 32 of section 2.

[266] Additionally, we are moving current Question 31 (base currency) and current Question 49 (withdrawals and redemptions) required only for qualifying hedge funds to section 1b, which is required to be completed by all advisers, and redesignating them as Question 17 and Question 10(d), respectively. We are also adopting amendments to enhance section 1c to require more detailed information about hedge funds' borrowing and financing arrangements (including posted collateral) and also revising current Question 26 (redesignated Question 32) and current Question 27 (redesignated Question 34) to require end of period reporting of the value of certain instrument categories (including listed equities, interest rate derivatives and other derivatives, and repo/reverse repos).

[267] In connection with the amendments, we are also removing current Question 44 because it is duplicative of the new reporting requirements in redesignated Question 32.

[268] *See* Form PF Frequently Asked Questions, *supra* footnote 162, Question 26.2.

[269] *See* Form PF Frequently Asked Questions, *supra* footnote 162, Question 26.5.

[270] The amendments to the sub-asset class list, as well as other changes to instructions in specific parts of Question 32, are discussed below.

provide additional explanatory information in situations where a qualifying hedge fund reports long or short dollar value exposure to ''catch-all'' sub-asset class categories [271] equal to or exceeding either (1) five percent of the reporting fund's net asset value or (2) $1 billion.[272] We have observed that some funds report significant amounts of assets in these ''catch-all'' categories. This new explanatory requirement will inform our understanding of significant exposure reported in these ''other'' sub-asset classes better, which is important for assessing systemic risk. One commenter recommended a threshold of 10 percent of a fund's net asset value, rather than five percent, for all reporting related to exposures, including to ''catch-all'' sub-asset classes.[273] We chose the five percent threshold level because it represents a level of exposure that is material to a fund's investment performance. We also continue to believe that the impact on a fund's returns resulting from an exposure of greater than five percent of its net asset value could be significant enough to present broader systemic risk and contagion risk. The $1 billion threshold represents a level for large funds (*e.g.,* those with net asset values in excess of $20 billion) that is large enough so as to have potential systemic risk implications even if the position is less than five percent of the fund's net asset value.

Separate reporting for positions held physically, synthetically or through derivatives and indirect exposure. We are adopting, as proposed except as specifically indicated below, amendments to require advisers to report the dollar value of a qualifying hedge fund's long positions and the dollar value of the fund's short positions in certain sub-asset classes by ''instrument type'' (*i.e.,* cash/physical instruments, futures, forwards, swaps, listed options, unlisted options, and other derivative products, ETFs, exchange traded products, U.S. registered investment companies (excluding ETFs and money market funds), non-U.S. registered investment companies, internal private fund or external private fund, commodity pool, or other company, fund, or entity).[274] For each month of the reporting period, advisers will be required to report long and short positions in these sub-asset classes held physically, synthetically or through derivatives, and indirectly through certain entities, separately in order to provide the Commissions and FSOC sufficient information to understand, monitor, and assess qualifying hedge funds' exposures to certain types of assets and investment products. The current instructions (and the associated definitions) require advisers to combine exposures held physically, synthetically, or through derivatives when reporting certain fixed income and other sub-asset classes.[275] Even when certain sub-asset classes currently separate physical and derivative exposures (*e.g.,* listed equities), all derivative instrument types are currently combined regardless of each derivative instrument type's risk characteristics. Furthermore, the form's current instructions for reporting investment exposure obtained through funds or other entities are different. For example, the current instructions require advisers to categorize ETFs based on the assets the ETF holds, while other registered investment companies are reported as a separate sub-asset class and may obscure the extent of a reporting fund's exposure to particular sub-asset classes.

As proposed, in determining the reporting fund's exposure to sub-asset classes for positions held indirectly through entities, advisers are permitted to allocate the position among sub-asset classes and instrument types using reasonable estimates consistent with their internal methodologies and conventions of service providers. In a modification from the proposal, advisers are also permitted to report an entirely indirectly held entity position in one sub-asset class and instrument type that best represents the sub-asset class exposure of the indirectly held entity, unless the adviser would allocate the exposure of the indirectly held entity more granularly under its own internal methodologies and conventions of its service providers.[276]

Some commenters stated that obtaining information about a fund's indirect exposures through investments in other funds could be difficult or

[271] These sub-asset classes include loans (excluding leveraged loans and repo), other structured products, other derivatives, other commodities, digital assets, and investments in other sub-asset classes.

[272] Some filers report significant exposure to these ''other'' categories. For example, the public Private Fund Statistics Q1 2023 (Table 46) shows about $153 billion in aggregate QHF GNE reported as ''other loans,'' more than other asset categories of interest, such as ABS/structured products (ex. MBS but excluding CLO/CDOs) (about $56 billion) and convertible bonds ($122 billion) as of Q1 2023. *See* Private Fund Statistics Q1 2023, *supra* footnote 5.

[273] *See* MFA Comment Letter II.

[274] *See* Form PF Glossary of Terms (definition of ''instrument type''). *See also* Question 32(a). Sub-asset classes that require reporting by instrument type (see Question 32(a)(1)) generally include: listed equity issued by financial institutions; American Depositary Receipts; other single name listed equity; indices on listed equity; other listed equity; unlisted equity issued by financial institutions; other unlisted equity; investment grade corporate bonds issued by financial institutions (other than convertible bonds); investment grade corporate bonds not issued by financial institutions (other than convertible bonds); non-investment grade corporate bonds issued by financial institutions (other than convertible bonds); non-investment grade corporate bonds not issued by financial institutions (other than convertible bonds); investment grade convertible bonds issued by financial institutions; investment grade convertible bonds not issued by financial institutions; non-investment grade convertible bonds issued by financial institutions; non-investment grade convertible bonds not issued by financial institutions; U.S. Treasury bills; U.S. Treasury notes and bonds; agency securities; GSE bonds; sovereign bonds issued by G10 countries other than the U.S; other sovereign bonds (including supranational bonds); U.S. state and local bonds; MBS; ABCP; CDO (senior or higher); CDO (mezzanine); CDO (junior equity); CLO (senior or higher); CLO (mezzanine); CLO (junior equity); other ABS; other structured products; U.S. dollar interest rate derivatives; non-U.S. currency interest rate derivatives; foreign exchange derivatives; correlation derivatives; inflation derivatives; volatility derivatives; variance derivatives; other derivatives; agricultural commodities; crude oil commodities; natural gas commodities; power and other energy commodities; gold commodities; other (non-gold) precious metal commodities; base metal commodities; other commodities; real estate; digital assets; investments in other sub-asset classes. These sub-asset classes are reported at the sub-asset class level and not by instrument type (*see* Question 32(a)(2)): leveraged loans; loans (excluding leveraged loans and repo); overnight repo; term repo (other than overnight); open repo; sovereign single name CDS; financial institution single name CDS; other single name CDS; index CDS; exotic CDS; U.S. currency holdings; non-U.S. currency holdings; certificates of deposit; other deposits; money market funds; other cash and cash equivalents (excluding bank deposits, certificates of deposit, and money market funds). We are also amending the Glossary of Terms to (i) amend the definitions of agency securities, convertible bonds, corporate bonds, GSE bonds, leveraged loans, sovereign bonds, and U.S. Treasury securities, in each case to include positions held indirectly through another entity, (ii) remove the definitions of crude oil, derivative exposures to unlisted equities, gold, natural gas, and power, and (iii) amend the definitions of commodities and other commodities. *See* Form PF Glossary of Terms. Additionally, for foreign exchange derivatives, advisers will be required to report foreign exchange swaps and currency swaps separately, and in determining dollar value, will not net long and short positions within sub-asset classes or instrument types (with the exception of spot foreign exchange longs and shorts).

[275] Advisers are required to report the dollar value of long and short positions for the sub-asset class (and not instrument type) for the following sub-asset classes: leveraged loans, loans (excluding leveraged loans and repo); overnight repo, term repo (other than overnight), open repo, sovereign single name CDS, financial institution single name CDS, other single name CDS, index CDS, exotic CDS, U.S. currency holdings, non-U.S. currency holdings, certificates of deposit, other deposits, money market funds, and other cash and cash equivalents (excluding bank deposits, certificates of deposit, and money market funds). *See* Question 32(a).

[276] The proposed instructions would limit the ''best represents'' standard to reporting of positions that represent both less than (1) 5% of the reporting fund's net asset value and (2) $1 billion. The adopted instruction removes the proposed position size condition and applies the ''best represents'' standard to all indirectly held exposures.

burdensome.[277] One commenter recommended allowing an adviser to select the sub-asset class that ''best represents'' the position.[278] We believe that adopting a ''best represents'' standard, regardless of the position size, balances the importance of obtaining more accurate and granular data with a reporting standard that is less burdensome for advisers than the proposed standard.

The increased granularity in reporting will allow for a better understanding of the activities of qualifying hedge funds and increase the utility of data collected for purposes of understanding the role qualifying hedge funds play in certain market events. For example, when monitoring funds' activities during recent market events like the March 2020 COVID–19 turmoil, the existing aggregation of U.S. treasury securities with related derivatives did not reflect the role hedge funds played in the U.S treasury market. Some commenters supported the proposed amendments to require hedge fund advisers to report their long and short holdings on a disaggregated basis.[279] One commenter stated that requiring private fund advisers to report both long and short positions will allow FSOC to have a complete picture of the risk exposure across private funds.[280] Another commenter supported disaggregated reporting of physical and synthetically held positions, stating that allowing advisers to aggregate their positions between physically held and synthetically held positions can make it difficult to understand the impact of hedge fund activity especially during periods of market instability.[281] We agree that the existing reporting, which allows advisers to aggregate their physical and synthetically held positions, as well as long and short exposures, obscures our understanding of the fund's overall exposure because of the risk differences between such holdings, which reduces our ability to effectively assess systemic risk. One commenter stated that more granular disclosure of long and short holdings can help ensure that FSOC has a complete understanding of systemic risk across private funds.[282] Another commenter opposed all proposed requirements to report additional monthly data, including the proposed requirement to provide additional monthly exposure reporting, on the basis that such monthly data would be costly to produce and would not be more beneficial than the existing quarterly basis reporting requirements.[283] Obtaining more granular data on a hedge fund's long and short positions is needed in order to provide the Commissions and FSOC sufficient information to understand, monitor, and assess qualifying hedge funds' exposures and assess systemic risk. Further, receiving this data on a monthly basis, rather than only as of quarter end, will give us better insight into trends that may indicate systemic risk. One commenter recommended that the Commissions define ''synthetic long position'' and ''synthetic short position'' and include a threshold for when a position is considered deep-in-the-money.[284] As discussed more fully in section II.B.2 above, we are adopting definitions for ''synthetic long position'' and ''synthetic short position'' in the Glossary of Terms and specifying as an example when a position is considered deep-in-the-money.

Adjusted exposure reporting. While we will continue to require advisers to report ''gross'' long and short exposure, *i.e.,* the dollar value of a qualifying hedge fund's long positions and dollar value of the fund's short positions for various sub-asset classes (and by instrument type for certain sub-asset classes as explained above), we are adopting, as proposed, amendments to require advisers to also report the ''adjusted'' exposure of long and short positions for each sub-asset class in which a fund has a reportable position.[285] Based on our experience, we have found that gross exposure reporting, while useful because the information indicates fund size on a comparable basis among funds, may inflate some qualifying hedge funds' reported long and short exposures in a way that does not properly represent the economic exposure and market risk of a reporting fund's portfolio. For example, when only looking at gross exposure, certain relative value strategies that are designed to match long and short exposures in the same or similar (highly correlated) assets may reflect very high leverage, but not have the same level of risk as portfolios with less leverage but that are more exposed directionally. Furthermore, some advisers, for purposes of managing risk, do not view their portfolio on a ''gross'' basis because they do not believe it provides a meaningful measure of risk. ''Gross'' exposure reporting by itself presents an incomplete picture that represents a significant data gap for purposes of systemic risk analysis.

Advisers will be required to determine adjusted exposure for each ''sub-asset'' using a specified methodology that is designed to facilitate comparisons of the reported data, as proposed. Specifically, advisers will be required to calculate and report ''adjusted exposure'' of long and short positions for each sub-asset class by netting (1) positions that have the same underlying ''reference asset'' across ''instrument type'' (*i.e.,* cash/physical instruments, futures, forwards, swaps, listed options, unlisted options, other derivative products, and positions held indirectly through another entity such as ETFs, other exchange traded products,[286] U.S. registered investment companies (excluding ETFs and money market funds), investments in non-U.S. registered investment companies,[287] other private funds, commodity pools, or other companies, funds or entities)and (2) fixed income positions that fall within certain predefined maturity buckets (*i.e.,* 0 to 1 year, 1 to 2 year, 2 to 5 year, 5 to 10 year, 10 to 15 year, 15 to 20 year, and 20+ year).[288]

[277] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter.

[278] MFA Comment Letter II.

[279] *See* AFREF Comment Letter I; Better Markets Comment Letter.

[280] AFREF Comment Letter I.

[281] *See* Better Markets Comment Letter.

[282] AFREF Comment Letter I.

[283] SIFMA Comment Letter.

[284] MFA Comment Letter II.

[285] Question 32(b). *See also* Form PF Glossary of Terms (definition of ''adjusted exposure'').

[286] In connection with this amendment, as proposed, we are also defining ''exchange traded product'' as ''an investment traded on a stock exchange that invests in underlying securities or assets, such as an ETF or exchange traded note.'' *See* Form PF Glossary of Terms. Given that the exchange traded product market has grown significantly since Form PF was first adopted, we believe that activity in exchange traded products may present different systemic risks than traditional listed equities and other instruments that might be used to obtain exposure to underlying assets owned within an ETF. Furthermore, we believe added insight into whether the underlying sub-asset class exposure is held through an ETF will enhance FSOC's analysis of systemic risk associated with this asset class.

[287] *See* Form PF Glossary of Terms (definition of ''investments in non-U.S. registered investment companies''). Furthermore, we are also removing the term ''U.S. registered investment companies'' from the Form PF Glossary of Terms.

[288] *See* Form PF Glossary of Terms. We are adopting, as proposed, a definition of ''reference asset'' as a security or other investment asset to which a fund is exposed through direct ownership (*i.e.,* a physical or cash position), synthetically (*i.e.* the subject of a derivative or similar instrument held by the fund), or indirect ownership (*e.g.,* through ETFs, other exchange traded products, U.S. registered investment companies, non-U.S. registered investment companies, internal private funds, external private funds, commodity pools, or other companies, funds, or entities). An adviser may identify a reporting fund's reference assets according to its internal methodologies and the conventions of service providers, provided that these methodologies and conventions are consistently applied, do not conflict with any instructions or guidance relating to Form PF and reported information is consistent with information it reports internally and to investors and

Continued

For purposes of determining ''adjusted exposure,'' a fund may use cross counterparty netting consistent with information reported by the fund internally and to current and prospective investors, because we believe it better reflects the fund's economic exposure. For example, a fund with market-neutral trades may lose substantial amounts of capital in a period of market stress if prices diverge, regardless of the identities of the counterparties. Additionally, counterparty identification may be ambiguous for some positions, such as when a fund simply has a long position in an equity security traded over an exchange or purchased from a broker without the use of any financing.

Finally, if a fund does not net across all instrument types in monitoring the economic exposure of the fund's investment positions for purposes of internal reporting and reporting to investors, we will (in addition to adjusted exposure determined as specified above) also require the adviser to report adjusted exposure based on an adviser's internal methodology and describe in Question 4 how the adviser's internal methodology differs from the standard approach in Question 32. This additional information will provide better insight into how these advisers assess the economic exposure of their reporting fund's portfolio, while still ensuring an adviser provides information that supports our and FSOC's ability to aggregate and compare the data across funds.

One commenter stated that the prescribed methodology for calculating netted exposure would be burdensome and that the Commissions underestimated the costs associated with this calculation.[289] One commenter stated that requiring monthly sub-asset class information, including adjusted exposure data, would not facilitate systemic risk monitoring because existing quarterly reporting provides the Commissions with similar information.[290] Receiving exposure data on a monthly basis will allow us to better understand interim changes in exposures that may be relevant to systemic risk assessment that are not visible from the existing quarterly data.[291] As discussed more fully in section IV.C below, identifying sub-asset classes will not be significantly burdensome because advisers will generally only need to make this determination once, with ongoing monitoring (and any reclassifications) relatively limited.[292] Further, because a fund may use cross counterparty netting consistent with information reported by the fund internally for purposes of determining adjusted exposure, the adjusted exposure reporting should not be significantly burdensome, particularly for funds using common aggregator protocols, because a fund can leverage its existing internal reporting methodology.

Require advisers to report a uniform interest rate risk measure. We are adopting, as proposed, amendments to require advisers to report the 10-year zero coupon bond equivalent [293] for all sub-asset classes with interest rate risk (by instrument type if applicable) [294] rather than providing advisers with a choice to report duration, weighted average tenor (''WAT''), or an unspecified 10-year bond equivalent.[295] Advisers will be required to report the 10-year zero coupon bond equivalent of the dollar value of long and short positions in each sub-asset class (and by instrument type, if applicable) as well as for the adjusted exposure of long and short exposures for each sub-asset class for each monthly period.

The amendment will improve reporting and allow us to obtain better data, because the current approach, while providing optionality, makes it difficult to compare and aggregate data reported by different funds effectively. Furthermore, the 10-year zero coupon bond equivalent is appropriate because it is commonly used by hedge fund advisers and will be a better and more consistent measure of interest rate risk than duration, WAT, or the current unspecified 10-year equivalent. WAT may be an incomplete measure because it does not always reflect the presence of options embedded in bonds or differing sensitivity to interest rate changes in circumstances where base currencies are subject to a higher or lower risk-free rate, and it also may not be meaningful for interest rate derivative products. Duration can tend toward infinity for certain derivatives and so can provide little meaning or utility. In addition, methodologies for calculations of duration and a 10-year equivalent (if not standardized to a zero coupon bond) may vary, which can result in variability among calculations, and requiring use of the 10-year zero coupon bond equivalent will provide comparability across the reported data. Therefore, eliminating additional reporting options and requiring the 10-year zero coupon bond equivalent will provide a common denominator across funds that advisers will be able to easily calculate and that will provide a consistent and comparable metric. In this regard, the requirement should not create an additional burden for advisers that currently report based on a 10-year equivalent for these types of assets, which we estimate represents roughly 42 percent of the total number of advisers responding to Question 32.[296]

One commenter stated that because the definition of ''10-year bond equivalent'' specifies the expression in the fund's base currency, for transactions not in the fund's base currency, there would need to be a foreign exchange conversion into the base currency and an additional conversion into U.S. dollars for certain questions, which would be burdensome.[297] As discussed further below in section II.D below, we are modifying the ''10-year bond equivalent'' definition to reference U.S. dollars, rather than the reporting fund's base currency. Therefore, an adviser in this scenario would not be required to

counterparties. In a change from the proposal, we are modifying the defined maturity buckets to remove the 10 -year and 15-year buckets to reduce potential confusion.

[289] MFA Comment Letter II.

[290] SIFMA Comment Letter.

[291] *See infra* section IV.C of this Release for discussion of costs and benefits.

[292] *Id. See also infra* section V of this Release for discussion of our increased cost estimates.

[293] As discussed further below in section II.D of this Release, we are adopting, with a modification from the proposal, a new glossary definition of 10-year bond equivalent to explain that the term 10-year bond equivalent means ''the equivalent position in a 10-year zero coupon bond, expressed in U.S. dollars.'' *See* Form PF Glossary of Terms (definition of ''10-year bond equivalent''). We are also making a conforming change to the definition of interest rate derivative to use this new definition.

[294] We are adopting amendments to require advisers to report the 10-year zero coupon bond equivalent for the following sub-asset classes: investment grade corporate bonds issued by financial institutions (other than convertible bonds); investment grade corporate bonds not issued by financial institutions (other than convertible bonds); non-investment grade corporate bonds issued by financial institutions (other than convertible bonds); non-investment grade corporate bonds not issued by financial institutions (other than convertible bonds); investment grade convertible bonds issued by financial institutions; investment grade convertible bonds not issued by financial institutions; non-investment grade convertible bonds issued by financial institutions; non-investment grade convertible bonds not issued by financial institutions; U.S. Treasury bills; U.S. Treasury notes and bonds; U.S. agency securities; GSE bonds; sovereign bonds issued by G10 countries other than the U.S; other sovereign bonds (including supranational bonds); U.S. state and local bonds; leveraged loans; loans (excluding leveraged loans and repo); overnight repo; term repo (other than overnight); open repo; MBS; ABCP; Senior or higher CDO; Mezzanine CDO; Junior equity CDO; Senior or higher CLO; Mezzanine CLO; Junior equity CLO; other ABS; other structured products ; U.S. dollar interest rate derivatives; non-U.S. currency interest rate derivatives; and certificates of deposit. *See* Question 32(c).

[295] *See* Question 32(c).

[296] Based on analysis of Form PF data 2022Q4, 2021Q4, and 2020Q4.

[297] *See* AIMA/ACC Comment Letter.

perform any additional exchange conversions.

Amended list of sub-asset classes.

We are adopting, as proposed, amendments to the list of reportable sub-asset classes in Question 32 in two respects. First, some sub-asset classes are consolidated and tailored to reflect the adopted reporting of the dollar value of long and short positions by instrument type. For example, sub-asset classes for listed and unlisted equity derivatives are combined with sub-asset classes for listed and unlisted equities, and similarly, sub-asset classes for physical commodities and commodity derivatives are combined.[298] Likewise, some current sub-asset classes will now be reflected as instrument types, such as internal private funds, external private funds, and registered investment companies (now separated into ETFs, U.S. registered investment companies, and non-U.S. registered investment companies). Second, we are adding new sub-asset classes to provide additional information to help the Commissions and FSOC better understand qualifying hedge funds' investment exposures to certain asset types and reduce reporting in certain ''catch-all'' sub-asset classes, such as ''other listed equity.''

We are also adopting amendments to: (1) expand equity exposure reporting to add sub-asset classes for (a) listed equity securities (including new sub-asset classes for other single name listed equities and indices on listed equities), and (b) American depository receipts (''ADRs''); (2) add additional sub-asset classes for reporting ''repo'' and ''reverse repo'' positions, based on term; (3) add additional sub-asset classes for asset backed securities (''ABS'') and other structured products; (4) add new sub-asset classes and revise existing sub-asset classes that capture certain derivatives, including certain credit derivatives and volatility and variance derivatives; (5) specify sub-asset classes pertaining to investments in cash and cash equivalents and commodities; and (6) add a new sub-asset class for digital assets.

One commenter opposed requiring more detailed disclosure of a fund's holdings and recommended that the Commissions leverage existing data sources, such as existing Form PF, Form 13F and 13H, and CFTC Form CPO–PQR reporting, to obtain more granular information about a fund's holdings.[299] We disagree that existing data sources can provide the amended fund-specific sub-asset class information. As discussed above, we have identified information gaps in the data reported on the existing Form PF based on our experience. From these data sets, we are unable to determine the full extent of a fund's exposure because the different types of exposures are combined, despite different exposures having differing risk characteristics.[300] This commenter also stated that the requirement to report more granular sub-asset class data would be overly burdensome and costly to report and that we should use other data sources for this information.[301] These amendments to the sub-asset class list more accurately reflect a fund's holding than other data sources and current Form PF reporting, which does not provide this level of specificity. Identifying sub-asset classes will not be significantly burdensome to report because advisers will generally only have to make this determination once and their ongoing monitoring (and any reclassifications) should be relatively limited. This commenter also raised confidentiality concerns and stated that the detailed sub-asset class data could enable a person with access to the data to recreate a private fund's investment strategy.[302] The asset class level data reported on Form PF, which is filed on a non-public basis, is not sufficiently detailed or reported on a basis frequent enough to present significant risk of misuse or enable reverse engineering of a particular fund's investment strategy.

Listed equity securities.

We are adding, as proposed, new sub-asset classes for certain categories of listed equity securities, specifically, for other single name listed equities and indices on listed equities. This change will provide more granularity to reporting on listed equities[303] given the potential impact of these new sub-asset classes from an overall systemic risk perspective, as the form currently only requires advisers to single out and report listed equities issued by financial institutions with all other listed equities reported in a catch-all category ''other listed equity.'' Identifying single equities separately from equity index exposure can help distinguish broadly diversified portfolios from those that could be more concentrated and also help to identify what strategies are being pursued by multi-strategy funds. Additionally, single equity positions may be more vulnerable to short squeezes than index positions, so this level of granularity will help to better identify entities that may be affected during a short squeeze event.[304]

One commenter stated that the proposed instructions do not specify whether the reporting fund's listed equity security holdings should include both the reporting fund's holding in shares of an ETF as well as the listed equity holdings of the same ETF.[305] Another commenter stated that the proposed question is unclear how advisers should report indirect holdings, such as positions held through entities such as ETFs, and recommended permitting advisers to allocate its exposures using any reasonable methodology.[306] In consideration of this comment, we are adopting instructions to Question 32 to provide that in determining a reporting fund's exposure to sub-asset classes for positions held indirectly through entities, such as through an ETF, the adviser may allocate the position among sub-asset classes and instrument types using reasonable estimates consistent with the adviser's internal methodologies and conventions of service providers, and the adviser may

[298] In connection with these amendments, we are amending the definitions of ''listed equity'' and ''unlisted equity'' to reflect that filers should include synthetic or derivative exposure as well as positions held indirectly through another entity (*e.g.,* through an ETF, exchange traded product, U.S.-registered investment companies, non-U.S. registered investment companies, internal private fund or external private fund, commodity pool, or other company, fund, or entity). Additionally, we are amending the definition of ''listed equity derivatives'' to include derivatives relating to ADRs, and other derivatives relating to indices on listed equities. *See* Form PF Glossary of Terms (definition of ''listed equity,'' ''unlisted equity,'' and ''listed equity derivatives'').

[299] *See* SIFMA Comment Letter.

[300] For example, Forms 13F and 13H do not collect fund-specific information, and only a small sub-set of Form PF filers (commodity pool operators and commodity trading advisors) are required to file Form CPO–PQR. As discussed above, we have identified information gaps in the data reported on the existing Form PF based on our experience.

[301] *See* SIFMA Comment Letter. *See also infra* at section IV.C of this Release for discussion of costs and benefits.

[302] *See* SIFMA Comment Letter.

[303] *See* current Question 26 and Question 30, which required reporting on listed equities but did not separate out single names from indices. Investments in single name equities involve materially more idiosyncratic risks, such as the potential for more extreme price movements that are not correlated to other market movements, than investments in indices, and therefore we have adopted amendments to require separate reporting.

[304] A short squeeze is a type of manipulation in which prices are manipulated upward to force short sellers out of their positions, as short sellers are required by brokers to maintain margin above a certain level, and as prices rise short sellers must add cash to their margin accounts or close out their short positions. Single stock shorts often account for a higher portion of the available float and/or often have a larger period of days to cover (*i.e.,* the number of trading days to cover a short) than do shorts on ETFs. As a result, a potential need to cover a short could generally have a more pronounced effect on single stocks.

[305] AIMA/ACC Comment Letter.

[306] MFA Comment Letter II.

report an entirely indirectly held entity position in one sub-asset class and instrument type that best represents the sub-asset class exposure of the indirectly held entity unless the adviser would allocate the exposure of the indirectly held entity more granularly under the adviser's own internal methodologies and conventions of its service providers.[307]

ADRs.

We are adding, as proposed, a new sub-asset class for ADRs in line with how ADRs are reported on the CFTC's Form CPO–PQR.[308] While ADRs are purchased in U.S. dollars, these instruments have currency risk because the underlying security is priced in its home country currency, and the ADR's U.S. dollar price fluctuates one-for-one with each movement in the home currency. Accordingly, advisers will be required to report ADRs separately from other listed equity instruments. This requirement also will help increase the utility of the information reported under the ''other listed equity'' sub-asset class on Form PF, which requires reporting of multiple other sub-asset classes. We did not receive comment on the proposed addition of an ADR sub-asset class.

Repurchase Agreements (''Repos'').

We are adding, as proposed, additional sub-asset classes to the ''repos'' section of Question 32 to capture a breakdown of repos by term (*e.g.,* overnight, other than overnight, and open term). Hedge funds often borrow cash overnight and pledge securities such as government bonds as collateral. Collecting more information on the different types of repos held by qualifying hedge funds will allow the Commissions and FSOC to understand better the role of these funds in potentially amplifying funding stresses and the risks associated with short-term funding for certain trading strategies, particularly in light of the issues the repo market experienced during the fall of 2019 and in March 2020.[309] We did not receive comment on adding sub-asset classes for repos.

Asset Backed Securities (''ABS'')/ structured products.

As proposed, we are separating the collateralized debt obligation (''CDO'') and collateralized loan obligation (''CLO'') sub-asset class in Question 32 into two separate sub-asset classes (one for CDOs and one for CLOs), and further breaking out each of these new sub-asset classes based on the seniority of the instrument (*e.g.,* senior, mezzanine, and junior tranches) similar to the reporting approach on the CFTC's Form CPO–PQR.[310] The changes are designed to provide separate reporting for CDOs and CLOs, which is important because CDOs and CLOs are fundamentally different financial products and the current combined reporting obscures the specific attributes of each product.

One commenter supported the disclosure of CDOs and CLOs as separate sub-asset classes because of the different investment and risk characteristics of these assets and the systemic risks associated with both asset classes.[311] We agree. Furthermore, given the recent focus on CLOs by FSOC [312] in monitoring systemic risk, having detailed product specific data for CDOs and CLOs is justified due to the potential value this information can provide for systemic risk monitoring.

Credit, Foreign Exchange, Interest Rate, and Other Derivatives.

We are revising, as proposed, the credit, foreign exchange, and interest rate and other derivative sub-asset classes to provide more detailed reporting. For example, with respect to credit derivatives, the amended sub-asset classes will collect more detail on single name CDS exposure to capture better information on risk signals from these instruments by adding separate sub-asset classes for sovereign single name CDS, financial institution single name CDS, and other single name CDS (to capture any credit derivatives that do not fall into the other enumerated CDS categories).[313] An increase in single name CDS exposure may signify a bet against an entity or the market more generally, which may have significant systemic risk implications, particularly with respect to concentrated single-issuer positions that can drive more extreme price movements and face difficulties in the unwinding process, and for counterparties on the other side of highly leveraged trades when the market moves against these positions.[314] Furthermore, single name CDS exposure can represent important, concentrated risk positions for a fund, similar to large single equity positions, which can be connected to market contagion events, and have systemic risk and market liquidity implications.

Similarly, we are adding more detailed reporting for foreign exchange derivatives by adding separate sub-asset classes for foreign exchange swaps and currency swaps consistent with reporting to the Bank for International Settlements (''BIS''), while removing the less useful requirement of separate reporting for foreign exchange derivatives used for investment and hedging, as we have found the data of limited value because we do not believe that information is reported consistently across filers.[315] Adding separate reporting for different types of foreign exchange instruments (*e.g.,* foreign exchange swaps and currency swaps) is appropriate because they have materially different risk characteristics, including different maturity profiles, and may be executed under different documentation which could affect their ability to be netted against one another. We refer to the BIS framework because we understand that it reflects a commonly accepted industry approach for classifying these instruments. Furthermore, given the significance of hedge funds' exposure to these instruments, more granular information will better inform our understanding of systemic risk issues that may arise from

[307] *See* Question 32.

[308] As noted above, where applicable, we are adopting amendments to align Form PF with Form CPO–PQR to (1) enable filers that currently are required to file both Form PF and Form CPO–PQR independently to compile and use similar data in completing both forms, and (2) enable users of the reported data (*e.g.,* FSOC and other regulatory agencies) to (i) link data for funds that file both forms, and (ii) aggregate and compare data across data sets more easily.

[309] *See, e.g.,* 2021 Financial Stability Oversight Council Annual Report at 12 and 159, *available at https://home.treasury.gov/system/files/261/FSOC2021AnnualReport.pdf.*

[310] *See* Form PF Glossary of Terms (definitions of ''CDO'' and ''CLO''). We are separating the current definition of ''CDO/CLO'' into a separate definition for each financial product. The definition of CDO only includes collateralized debt obligations (including cash flow and synthetic) and the definition of CLO includes collateralized loan obligations (including cash flow and synthetic) other than MBS and does not include any positions held via CDS. *See also supra* footnote 308 (regarding the alignment of Form PF with Form CPO–PQR).

[311] NASAA Comment Letter.

[312] *See* United States Government Accountability Office, Report to Agency Officials, ''FINANCIAL STABILITY Agencies Have Not Found Leveraged Lending to Significantly Threaten Stability but Remain Cautious Amid Pandemic,'' Dec. 2020, *available at https://www.gao.gov/assets/gao-21-167.pdf.*

[313] *See also* Form PF Glossary of Terms (revised definition of ''single name CDS''). We are also removing ''credit derivatives'' and ''risk limiting conditions'' as defined terms because they are no longer used in the form.

[314] The CFTC's Form CPO–PQR also requests information on single name financial CDS, and the revised IOSCO Global Fund Investment Survey also collects this information.

[315] In connection with these changes, we are also adopting changes to the definition of ''foreign exchange derivative'' to improve data quality with respect to how advisers report foreign exchange derivative exposure. We are revising the definition to (1) now include any derivative whose underlying asset is a currency other than the base currency of the reporting fund, (2) provide additional information on the treatment of cross-foreign exchange versus regular foreign exchange, and (3) require reporting of both legs of cross currency foreign exchange derivatives to reflect exposures from such transactions. *See* Form PF Glossary of Terms (revised definition of ''foreign exchange derivative'').

holdings in these different types of instruments.

We are also dividing the current ''interest rate derivatives'' sub-asset class into ''U.S. dollar interest rate derivatives'' and ''non-U.S. currency interest rate derivatives.'' This added sub-asset class granularity is important because we have found that Form PF data consistently shows interest rate derivatives as the sub-asset class to which qualifying hedge funds have the greatest exposure over time. A better understanding of whether these exposures are related to the U.S. dollar yield curve or other countries' yield curves is important from a systemic risk analysis perspective. Finally, we are adding new sub-asset classes for various types of derivatives that are regularly used by hedge funds including correlation derivatives, inflation derivatives, volatility derivatives, and variance derivatives, which will both provide additional insight into how qualifying hedge funds use these types of financial instruments and further limit the number and type of derivatives that advisers report in the ''catch-all'' ''other derivatives'' category.[316]

More detailed reporting of currency exposure arising from foreign exchange derivatives is important for systemic risk. The requirement to select the sub-asset class that best represents the investment will address concerns about any burdens associated with obtaining this information.

Although one commenter generally opposed the inclusion of additional sub-asset classes,[317] we did not receive comment on these particular sub-asset class revisions. As discussed more fully above in the context of particular amendments to the sub-asset class list, the amendments to the sub-asset class list that we are adopting more accurately reflect a fund's holding than other data sources and current Form PF reporting and are important for systemic risk analysis. Understanding sub-asset class exposure on a more granular level will enhance our understanding of qualifying hedge funds' investment exposures to different asset classes and instruments that may present different systemic risks. These amendments will also enhance data quality by reducing the asset reporting that is currently made in ''catch-all'' categories or less precise categories, such as a sovereign single name CDS that would currently be categorized more generically as a single name CDS.

Cash and Commodities.

We are adopting, as proposed, revisions to the sub-asset class categories for cash and commodities. We are adopting amendments to require advisers to break out cash and cash equivalents [318] between U.S. currency holdings and non-U.S. currency holdings, while also removing the current requirement to report on investments in funds for cash management purposes (other than money market funds) because in our experience advisers use inconsistent methods for determining whether a private fund investment is being used for cash management purposes and other information reported in section 2 is more useful for assessing liquidity management (*e.g.,* Question 38 with respect to unencumbered cash).[319]

One commenter supported separate reporting of U.S. Treasury security holdings and cash and cash equivalents on the basis that including these asset classes together can obscure information about a fund's holdings.[320] Another commenter opposed the proposed revision to the definition of ''cash and cash equivalents'' to remove treasury securities on the basis that such an exclusion would be inconsistent with market practice of treating short-term treasury securities as a cash equivalent for risk management and cash management purposes.[321] It is important to understand a reporting fund's exposure to treasury securities distinct from its cash and cash equivalent holdings because of the different risk profiles of these asset categories, as demonstrated by recent market events.[322] We continue to believe that removing the treasury securities from the definition of ''cash and cash equivalents'' is appropriate and will provide more useful data and promote consistency across filers.

Additionally, we are broadening the current power commodity sub-asset classes to also capture other energy commodities and add additional commodity sub-asset classes (*e.g.,* other (non-gold) precious metals, agricultural commodities, and base metal commodities) to provide added granularity with respect to these financial products given their potential systemic risk implications and to better inform our and FSOC's understanding of the activities of hedge funds in these important commodities markets. We have found that a limitation of the current form is that very different commodities (*e.g.,* wheat and nickel) are reported together in the same sub-asset class (*i.e.,* ''other commodities'') making the reported data less meaningful for analysis. With added granularity, we will be in a better position to identify concentrated exposures to particular commodities, data that could be valuable in the event of a dislocation in a particular commodity market.[323] The additional commodity sub-asset classes that we are adding, *i.e.,* other (non-gold) precious metals, agricultural commodities, and base metal commodities, were chosen because they are most relevant from a systemic risk perspective given the size of these markets and what we currently know of hedge fund exposures to these markets.[324] We did not receive

[316] In connection with these amendments, we are also adding new definitions to the Glossary of Terms for ''correlation derivative,'' ''inflation derivative,'' ''volatility derivative,'' and ''variance derivative.'' *See* Form PF Glossary of Terms.

[317] *See* SIFMA Comment Letter.

[318] Some advisers include treasuries in their reporting of ''cash'' because it was part of the current definition of ''cash and cash equivalents.'' We are revising the definition of ''cash and cash equivalents'' to reflect that treasuries should not be included in the ''cash and cash equivalents'' sub-asset class. In connection with this change we also are adding a new separate definition for ''government securities.'' *See* Form PF Glossary of Terms (revised definition of ''cash and cash equivalents'' and definition of ''government securities''). *See also* discussion at section II.B.2 of this Release regarding the revised definitions of cash and cash equivalents and government securities.

[319] Additionally, in many cases we will be able to obtain more information about all internal fund investments (including whether a fund looks like a cash management vehicle) through the new information the amendments require to be reported in section 1b. *See* discussion at section II.B.2 of this Release.

[320] *See* AFREF Comment Letter I.

[321] MFA Comment Letter II.

[322] *See, e.g.,* Group of Thirty Working Group on Treasury Market Liquidity, *U.S. Treasury Markets: Steps Toward Increased Resilience,* (2021), *available at https://group30.org/publications/detail/4950* (discussing recent market stress events in the U.S. Treasury securities market).

[323] For example, we believe the addition of a base metal commodities sub-asset class will allow for identification of large players in the base metals market (such as those impacted by the Mar. 2022 ''nickel squeeze''). During the Mar. 2022 ''nickel squeeze,'' the price of nickel rose unusually steeply and rapidly in response to commodity price increases caused by Russia's invasion of Ukraine, and this event, coupled with one or more market participants holding large short positions, caused prices to increase in an extreme manner (*e.g.,* a one-day increase of 63% for the generic first futures contract on Mar. 7, 2022). *See, e.g.,* Shabalala, Zandi, Nickel booms on short squeeze while other metals retreat, Reuters (Mar. 2022), *available at https://www.reuters.com/markets/europe/lme-nickel-jumps-another-10-after-record-rally-supply-fears-2022-03-08/;* Nagarajan, Shalini, Nickel Trading Halted at LME Until Friday After Wild Price Spike (businessinsider.com) (Mar. 2022), *available at https://markets.businessinsider.com/news/commodities/nickel-price-london-metal-exchange-suspends-trading-shanghai-short-squeeze-2022-3#:~:text=The%20London%20Metal%20Exchange%20has,17%25%20to%20their%20daily%20limit.*

[324] These adopted changes with respect to commodities sub-asset classes will also better align Form PF with Form CPO–PQR.

comments on these proposed changes to the commodity sub-asset classes.

Digital Assets.

We are adopting, as proposed, a new sub-asset class for digital assets. However, as discussed more fully above in section II.B.3 of this Release, we are not adopting the proposed definition of ''digital assets.'' [325] We have observed the growth as well as the volatility of this asset class in recent years.[326] We understand that many hedge funds have been formed recently to invest in digital assets, while many existing hedge funds are also allocating a portion of their portfolios to digital assets.[327] Accordingly, it is important to collect information on funds' exposures to digital assets in order to understand better their overall market exposures. Although we are not adopting the proposed definition of ''digital assets'' at this time, we are adding an instruction to Question 32 that states if a particular asset could be classified as both a digital asset and another asset, the adviser should report the asset as the non-digital asset. For example, a money market fund that is traded on a blockchain should be reported as a money market fund, rather than as a digital asset. This is designed to reduce potential confusion, narrow the assets that are reported as digital assets under the form and improve data quality.

One commenter recommended requiring disclosure of digital asset exposure on a quarterly or biannual basis for all filers due to the general volatility of digital assets and the potential for systemic risk.[328] All large hedge fund advisers are required to file Form PF on a quarterly basis, so we will receive data on digital asset exposure from these filers on a quarterly basis. In addition, as discussed more fully above in section II.B.3 of this Release, we are adopting amendments which require all hedge fund advisers, including large hedge fund advisers, to disclose the reporting fund's use of digital asset investment strategies.

Open and Large Position Reporting.

We are adopting, as proposed, amendments to require advisers to qualifying hedge funds to report the top five long and short netted positions and the top ten netted long and short positions. This amendment will provide a holistic view of a reporting fund's portfolio concentration. We also understand that these are commonly used industry metrics for assessing portfolio concentration levels. We are defining ''netted exposure'' as the sum of all positions with legal and contractual rights that provide exposure to the same reference asset, taking into account all positions, including offsetting and partially offsetting positions, relating to the same reference asset (without regard to counterparties or issuers of a derivative or other instrument that reflects the price of the reference asset), as proposed.[329] Currently, advisers to qualifying hedge funds are required to report (1) a fund's total number of ''open positions'' determined on the basis of each position and not with reference to a particular issuer or counterparty,[330] and (2) the percentage of a fund's net asset value and sub-asset class for each open position that represents five percent or more of a fund's net asset value.[331] Advisers to qualifying hedge funds will now be required to report (1) the total number of reference assets to which a fund holds long and short netted exposure, (2) the percentage of net asset value represented by the aggregate netted exposures of reference assets with the top five long and short netted exposures, and (3) the percentage of net asset value represented by the aggregate netted exposures of reference assets representing the top ten long and short netted exposures. These amendments are designed to provide insight into the extent of a fund's portfolio concentration and large exposures to any reference assets. We have found that advisers use different methods for identifying and counting their ''open positions,'' which has made making meaningful comparisons among funds difficult. This has also potentially obscured certain large exposures, which may make concentration assessments less exact. For example, an ''open position'' might indicate a position held physically, or synthetically through derivatives, or both.

Advisers will also be required to provide certain information on a fund's reference asset to which the fund has gross exposure (as of the end of each month of the reporting period), largely as proposed, equal to or exceeding (1) one percent of net asset value, if the reference asset is a debt security and the reporting fund's gross exposure to the reference asset exceeds 20 percent of the size of the overall debt security issuance, (2) one percent of net asset value, if the reference asset is a listed equity and the reporting fund's gross exposure to the reference asset exceeds 20 percent of average daily trading volume measured over 90 days preceding the reporting date, or (3) (a) five percent of the reporting fund's net asset value or (b) $1 billion.[332] Advisers will be required to report: (1) the dollar value (in U.S. dollars) of all long and the dollar value (in U.S. dollars) of all short positions with legal and contractual rights that provide exposure to the reference asset; (2) netted exposure to the reference asset; (3) sub-asset class and instrument type; (4) the title or description of the reference asset; (5) the reference asset issuer (if any) name and LEI; (6) CUSIP (if any); [333] and (7) if the reference asset is a debt security, the size of issue, and if the reference asset is a listed equity, the average daily trading volume, measured over 90 days preceding the reporting date, as proposed. Additionally, advisers may at their option choose to provide the FIGI for the reference asset, but they are not required to do so.[334] We are defining ''gross exposure'' to a ''reference asset'' as the sum of the absolute value of all long and short positions with legal and contractual rights that provide exposure to the reference asset, as proposed.[335] We considered varying levels of thresholds and believe that the thresholds described above are appropriate based on the following

[325] *See* discussion at section II.B.3 of this Release.

[326] The global market for crypto assets is valued by some estimates at approximately $900 billion as of Dec. 2022. *See, e.g.,* Global Cryptocurrency Market Cap Charts, CoinGecko, *available at https://www.coingecko.com/en/global-charts* (last visited on Oct. 12, 2023). Volatility in the price of crypto assets has caused this number to fluctuate considerably over the past few years. For example, in July of 2020 the market was estimated to be worth approximately $276 billion, but went on to reach a peak value of approximately $3 trillion by Nov. 2021. *Id.*

[327] *See* C. Williamson, Managers Taking Bigger Steps Into Crypto, *Pensions & Investments* (Mar. 2022), *available at at https://www.pionline.com/cryptocurrency/hedge-fund-managers-taking-bigger-steps-cryptocurrehttps://www.pionline.com/cryptocurrency/hedge-fund-managers-taking-bigger-steps-cryptocurrency.*

[328] AFREF Comment Letter I.

[329] Netted exposure to a reference asset may either be long or short, and advisers will be required to determine the value of each netted exposure to each reference asset in U.S. dollars, expressed as the delta adjusted notional value, or as the 10-year bond equivalent for reference assets that are fixed income assets. Advisers will not report exposure to cash and cash equivalents. *See* Question 39. *See also* Form PF Glossary of Terms (definition of ''netted exposure'').

[330] Current Question 34.

[331] Current Question 35.

[332] In a modification from the proposal, the adopted instructions add reference to the size of the *overall* debt security issuance (emphasis added) to specify the appropriate calculation. Further, the reference to a ''listed equity security'' has been modified to ''listed equity'' to align with the defined term used in the Glossary of Terms.

[333] Advisers will also be required to provide at least one of the following other identifiers: (1) ISIN; (2) ticker if ISIN is not available); or (3) other unique identifier (if ticker and ISIN are not available). For reference assets with no CUSIP, or other identifier, advisers will be required to describe the reference asset. *See* Question 40(a).

[334] *See* Question 40(a)(xi).

[335] *See* Question 40 and Form PF Glossary of Terms (revised definition of ''gross exposure'').

reasoning. First, the five percent threshold has been carried over from the current version of Form PF and is also a commonly used metric for identifying significant positions in a portfolio.[336] In addition, while a portfolio is generally viewed as diversified when it holds at least 20 different positions, when a position goes above five percent it reduces portfolio diversification. Second, the $1 billion threshold represents a level for large funds (*e.g.,* those with net asset values in excess of $20 billion) that is large enough so as to have potential systemic risk implications even if the position is less than five percent of the fund. Finally, the one percent of net asset value and 20 percent of issuance or average trading volume thresholds are aimed at limiting filer burdens while still providing insight into the risks associated with a position that may be small relative to a fund's overall portfolio, but which constitutes a large fraction of the market for a particular holding, given that a liquidation by one fund can trigger a disorderly liquidation. A disorderly liquidation of this kind may raise systemic risk concerns as it may lead to liquidation losses at other funds for which the position is more impactful and possibly lead to a cascade of additional unwinds.

The purpose of these amendments is to improve our ability to assess the magnitude of hedge fund portfolio concentration, as well as to identify directional exposure. From a systemic risk and an investor protection perspective, high portfolio concentration carries the risk of amplified losses that can occur when a fund's investment represents a large portion of a particular investment, asset class, or market segment. Leveraged portfolios further amplify this risk. The amendments are designed to better capture a fund's concentration risk (*e.g.,* where gross exposure to a reference asset is large compared to the fund's NAV and/or compared to the market for a reference security). Reporting positions that are large compared to market size also may provide some insight about whether multiple firms are ''crowding'' into trades in certain types of securities or other financial assets. Such ''crowding'' may increase the risk that one fund's forced selling may trigger systemic effects across a particular market.

Collecting information about the composition of exposure to a reference asset will allow us and FSOC to link the information reported in Question 40 to exposure reporting in Question 32, which will give the reported data added context and facilitate understanding of a fund's investment portfolio and assessment of any implications for systemic risk and investor protection purposes. For example, in a convertible arbitrage trade involving a position in a convertible bond and an offsetting position in the equity securities of the same issuer, reference asset exposure might be obtained by positions in two different sub-asset classes (*i.e.,* investment grade convertible bonds and equities) and using a combination of instrument types (*e.g.,* physical ownership and futures or a swap). The combination of information reported in Question 32 and Question 40 will facilitate our ability to identify this type of situation, better understand a qualifying hedge fund's investment approach and whether it is taking on concentrated positions (potentially with leverage), and assess whether or not a qualifying hedge fund's activities may have systemic risk or investor protection implications.

One commenter stated that more granular disclosure of holdings, including both long and short positions, will provide a more complete picture of the risk exposure across private funds and can help the SEC enforce fraud and manipulation of security-based swaps.[337] Some commenters opposed the requirements for more detailed disclosure of holdings on the basis that more granular disclosure would be costly to report and is not needed for systemic risk assessment.[338] For reasons discussed above, more granular information about a fund's exposure to a reference asset will allow us and FSOC additional context to facilitate understanding of a fund's investment portfolio and assessment of any implications for systemic risk and investor protection purposes, which justifies any incremental cost to advisers. One commenter recommended not requiring reporting on exposures on a gross basis because of the potential for gross figures to overstate a fund's exposure.[339] Advisers are required to report exposures on a gross *and* net basis because reporting on either a gross or net basis only would limit our understanding of the total risk exposure, for example any basis risk of the exposure.

In response to a request for comment in the proposing release regarding the use of FIGI as a substitute for CUSIP, one commenter recommended the inclusion of FIGI as an alternative financial identifier in lieu of CUSIP in Question 40, which requires advisers to report CUSIP information for each reference asset, if available.[340] Two commenters opposed permitting the use of FIGI in lieu of CUSIP stating that CUSIP is a single fungible identifier, whereas FIGI is not a single fungible identifier and produces multiple identifiers depending on the venue of execution.[341] We agree that, for reporting on Form PF, a fungible identifier is preferable because it will allow for more consistent reporting of assets than a nonfungible identifier regardless of the venue of execution, resulting in more effective monitoring and assessment of systemic risk. We are not adopting a change to permit the substitution of FIGI for CUSIP. Question 40 continues to require advisers to report for each reference asset the CUSIP, if any, and at least one of the following identifiers: ISIN, ticker, if ISIN is not available, or other unique identifier, if ISIN and ticker are not available.[342] Advisers may, on an optional basis, report for each reference asset the FIGI.[343] For reference assets with no CUSIP or other identifier, advisers are required to describe the reference asset.[344]

b. Borrowing and Counterparty Exposure

Counterparty exposure. As noted above, we are revising and enhancing how advisers report information about their relationships with creditors and other counterparties (including CCPs) and the associated collateral arrangements for their hedge funds, largely as proposed.[345] For qualifying hedge funds, we are adopting, as proposed, a new consolidated counterparty exposure table, similar to the new consolidated counterparty exposure table adopted for hedge funds in section 1c of the form,[346] which will capture all cash, securities, and synthetic long and short positions by a reporting fund, a fund's credit exposure

[336] *E.g.,* Schedule 13G/13D uses a 5% threshold.

[337] AFREF Comment Letter I.

[338] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter; AIMA/ACC Comment Letter. *See infra* section IV.C of this Release for discussion of costs and benefits of the amendments.

[339] MFA Comment Letter II.

[340] Bloomberg Comment Letter. Form PF Question 65 also requires large liquidity fund advisers to report the CUSIP number for each security held by the reporting fund and for each security subject to a repo.

[341] *See, e.g.,* American Bankers Association Comment Letter (Oct. 11, 2022); Comment Letter of CUSIP Global Services (Oct. 11, 2022).

[342] Question 40.

[343] *Id.*

[344] *Id.* We encourage advisers to obtain financial identifiers for all of their assets for the benefit of their investors when reporting their investments to regulatory authorities and others.

[345] *See* discussion at section II.B.3 of this Release.

[346] Id.

to counterparties, and amounts of collateral posted and received. This table replaces the information currently required by current Questions 43, 44, 45, and 47, each of which has been deleted.[347] Questions 42 and 43 will continue to collect information about a reporting fund's key individual counterparties, but in more detail. These revisions are designed to improve data quality and comparability, close data gaps, and provide better insight into qualifying hedge funds' borrowing and financing relationships, their credit exposure to counterparties and collateral practices. They also will enhance the Commissions' and FSOC's ability to assess the activities of qualifying hedge funds and their counterparties for investor protection purposes and in monitoring systemic risk.

The new consolidated counterparty exposure table is designed to capture information on all non-portfolio credit exposure that a qualifying hedge fund has to its counterparties (including CCPs) and the exposure that creditors and other counterparties have to the fund, taking into account netting. The new table requires advisers to report in U.S. dollars, as of the end of each month of the reporting period, a qualifying hedge fund's borrowings and other transactions with creditors and other counterparties by type of borrowing or transaction (*e.g.,* unsecured, secured borrowing and lending under a prime brokerage agreement, secured borrowing and lending via repo or reverse repo, other secured borrowing and lending, derivatives cleared by a CCP, and uncleared derivatives) and the collateral posted or received by a reporting fund in connection with each type of borrowing or other transaction.[348] The table also requires advisers to qualifying hedge funds to (1) classify each type of borrowing by creditor type (*i.e.,* U.S. depository institution, U.S. creditors that are not depository institutions, and non-U.S. creditors); (2) classify posted collateral by type (*e.g.,* cash and cash equivalents, government securities, securities other than cash and cash equivalents and government securities and other types of collateral or credit support (including the face amount of letters of credit and similar third party credit support) received and posted by a reporting fund, and secured borrowing and lending (prime brokerage or other brokerage agreement)), and (3) report, at the end of each month of the reporting period, the expected increase in collateral required to be posted by the reporting fund if the margin increases by one percent of position size for each type of borrowing or other transaction, as proposed. Measuring the impact of a one percent margin change will allow for a meaningful assessment of qualifying hedge funds' vulnerability to changes in financing costs and identification of funds that are most sensitive to potential margin changes. We also believe that measuring this impact will provide a standardized way to obtain data on funds' vulnerability to margin increases that is easy to scale up for analysis purposes and allows for uniform comparisons across hedge funds to see which funds have lockup agreements and which funds do not. Furthermore, the table consolidates current Questions and provides more specific instructions in an effort to eliminate information gaps and improve the reliability of data collected. This new approach will collect better information about a qualifying hedge fund's borrowing and financing, cleared and uncleared derivatives positions, and collateral practices as well as a fund's credit exposure to counterparties resulting from excess margin, haircuts, and positive mark-to-market derivatives transactions, which will enhance FSOC's systemic risk assessments.

Some commenters opposed the requirement to provide additional detail regarding counterparty exposure and stated that the information would be burdensome and costly to obtain.[349] We continue to believe that disaggregated counterparty exposure is important to systemic risk monitoring efforts for the reasons discussed above. This information will not be significantly burdensome to produce as we understand knowledge of counterparties to be a component of a fund's basic risk management practices.

Significant counterparty reporting. We are adopting, as proposed except as specifically indicated below, amendments to require advisers, for each of their qualifying hedge funds, to identify all creditors and counterparties (including CCPs) where the amount a fund has borrowed (including any synthetic long positions) before posted collateral equals or is greater than either (1) five percent of the fund's net asset value or (2) $1 billion.[350] This threshold is appropriate because it highlights two different but potentially significant risks. First, five percent of a fund's net asset value represents an amount of borrowing that, if repayment was required, could be a significant loss of financing that could result in a forced unwind and forced sales from the reporting fund's portfolio. Second, $1 billion represents an amount that, in the case of a very large fund, may not represent five percent of the fund's net asset value, but may be large enough to create stress for certain of its counterparties.

This change is designed to specify how securities held should be treated, avoiding a common source of error in how advisers have completed the current form, and allowing both counterparty risks related to collateralized transactions to be viewed in one place, *i.e.,* the risk that collateral will not be returned, and the risk that the borrower of cash will fail to repay the amount borrowed, risks that we have found cannot be fully observed

[347] In connection with the removal of current Question 44, we have made a corresponding amendment to current Question 13 (redesignated as Question 19), to remove an instruction that is no longer relevant.

[348] The instructions direct advisers to classify borrowings and other transactions and associated collateral based on the governing legal agreement (*e.g.,* a prime brokerage or other brokerage agreement for cash margin and securities lending and borrowing, a global master repurchase agreement for repo/reverse repo, and ISDA master agreement for synthetic long positions, synthetic short positions and other derivatives), and instruct advisers how to report when there is cross-margining under a fund's prime brokerage agreement. We are also adding new definitions of ''synthetic long position'' and ''synthetic short position'' to the Glossary of Terms. *See* Form PF Glossary of Terms (definitions of ''synthetic long position'' and ''synthetic short position''). Additionally, the instructions permit advisers to net a reporting fund's exposure with each counterparty and across affiliated entities of a counterparty to the extent such exposures may be contractually or legally set-off or netted across those entities and/or one affiliate guarantees or may otherwise be obligated to satisfy the obligations of another under the agreements governing the transactions. The instructions also direct advisers to classify borrowing by creditor type (*e.g.,* percentage borrowed from U.S depository institutions, U.S. creditors that are not U.S depository institutions, non-U.S. creditors) based on the legal entity that is the contractual counterparty for such borrowing and not based on parent company or other affiliated group.

[349] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter.

[350] *See* Question 42. Advisers will use calculations performed to complete the new table in Question 41 for purposes of identifying the counterparties to be reported in Question 42 and Question 43, and the calculation method is designed to be similar to the calculations used to identify counterparties in Question 27 and Question 28 in order to facilitate aggregation and analysis of data across hedge funds and qualifying hedge funds. Furthermore, if more than five counterparties meet the threshold, advisers will be required to complete an individual counterparty exposure table for the top five creditors or other counterparties to which a reporting fund owed the greatest amount in respect of cash borrowing entries (before posted collateral), and also identify all other creditors and counterparties (including CCPs) to which the reporting fund owed an amount in respect of cash borrowing entries (before posted collateral) equal to or greater than either (1) 5% of the reporting fund's net asset value as of the data reporting date or (2) $1 billion. *See also* Form PF Glossary of Terms (definitions of ''cash borrowing entries'' and ''collateral posted entries'').

based on information collected on the current form. For the top five creditors and other counterparties from which a fund has borrowed the most (including any synthetic long positions) before posted collateral, advisers will be required to identify the counterparty (by name, LEI, and financial institutional affiliation) and to provide information detailing a fund's transactions and the associated collateral. We are adopting a ''top five'' reporting threshold as this level is consistent with the current threshold for reporting on collateral practices on Form PF, and it represents a level that indicates significant counterparty exposure.[351]

Advisers will be required to present this information using an individual counterparty exposure [352] table that follows the same format as the new consolidated counterparty exposure table described above for Question 41, including borrowings and other transactions by type and collateral posted and received by type. For all other creditors and counterparties from which the amount a fund has borrowed (including any synthetic long positions) before posted collateral that equals or is greater than either (1) five percent of the fund's net asset value or (2) $1 billion, advisers will be required to identify each counterparty (by legal name, LEI, and financial institution affiliation) and report the amount of such borrowings and the collateral posted by the fund in U.S. dollars.[353]

As discussed more fully above in section II.A.2, we are adopting amendments that require advisers to report all trading vehicles on a consolidated basis. After considering one commenter's recommendation, we are tailoring certain questions about trading vehicles to help differentiate potential risks of the reporting fund from those of its trading vehicles.[354] In a modification from the proposal, we are adding an instruction to require advisers to list counterparty exposures of trading vehicles owned by the reporting fund based on the reporting fund's percentage ownership of such trading vehicle without netting these exposures with those of the reporting fund if they are not guaranteed by the reporting fund or contractual obligations of the reporting fund.[355] The amended instructions provide that the adviser must also report the legal name and LEI, if any, of the entity that has the counterparty exposure.[356] This amended instruction will allow us to better understand the scope of the reporting fund's exposure and differentiate its exposures from those held by a separate entity, such as a trading vehicle.[357]

As proposed, advisers will be required, for each of their qualifying hedge funds, to identify all counterparties (including CCPs) to which a fund has net mark-to-market counterparty credit exposure after collateral that equals or is greater than either (1) five percent of the fund's net asset value or (2) $1 billion.[358] This threshold is appropriate because both portions of the threshold highlight potential systemic risk: five percent of net asset value is a level that represents significant exposure (based on the impact on performance) in the event of counterparty default, and $1 billion, while it may not equal five percent of a large hedge fund's assets, may indicate a larger systemic stress involving a fund's counterparties. For the top five of these counterparties, advisers will be required to identify the counterparty (by name, LEI and financial institution affiliation) and provide information detailing a fund's relationship with these counterparties including associated collateral using the same table required for individual counterparty reporting.[359] In a modification from the proposal, advisers will also be required to report the borrowing by the reporting fund and the collateral posted by the reporting fund. These modifications are intended to align the question text with the information that is required to be reported in the counterparty exposure table. Further, in a modification from the proposal, an adviser will also be required to report the legal name of the entity that has the counterparty exposure and its LEI, if any. This modification will allow us to better understand the scope of the reporting fund's exposure and differentiate its exposures from those held by a separate entity, such as a trading vehicle. As proposed, advisers to qualifying hedge funds will also be required to identify all other counterparties (by name, LEI, and financial institution affiliation) to which a fund has net mark-to-market exposure after collateral that equals or is greater than either (1) five percent of a fund's net asset value or (2) $1 billion and will require these advisers to report the amount of the exposure before and after collateral posted by either the counterparty or the reporting fund as applicable, as proposed. Further, in a modification from the proposal, advisers will also be required to report the name and LEI, if any, of the entity that has the counterparty exposure. The purpose of this new requirement is to enhance our ability to understand the impact of a particular counterparty failure, such as the counterparty failures that occurred during the 2008 financial crisis and in the period since (*e.g.,* the failure of MF Global in 2011),[360] which is important for systemic risk assessments and from an investor protection perspective. In assessing the risk to a fund of a counterparty default, the new data will demonstrate whether a fund has net borrowing exposure or net lending exposure to a counterparty. If the fund is a net borrower with respect to a counterparty, we will measure cash borrowed by the fund against collateral posted by fund. Alternatively, when the fund is a net lender with respect to a counterparty, we will measure cash loaned to the counterparty against collateral posted by the counterparty to assess whether the counterparty has

[351] *See* Question 42.

[352] In connection with the amendment, we are adding a new definition for ''individual counterparty exposure table'' to the Form PF Glossary of Terms.

[353] In a change from the proposal, we have modified the reference from name to legal name to specify that the adviser should report the relevant counterparty's legal name. This modification will improve data comparability by enhancing our ability to track any individual counterparty reporting across filings. Further, in a change from the proposal, we have modified the question to specify that the adviser should report the legal name of the counterparty, the counterparty LEI, if any, the borrowing by the reporting fund, the collateral posted by the reporting fund, and the legal name of the entity that has the exposure and its LEI, if any. This modified question aligns the question's wording with the information that is required to be reported in the individual counterparty exposure tables that follow in the form.

[354] *See* Schulte Comment Letter.

[355] *See* Question 42. *See also* Questions 43 and 44 (requiring providing the legal name and LEI, if any, of the relevant entity with the exposure).

[356] *See* Question 42. If the reporting fund guarantees or is contractually obligated to fulfill obligations of a trading vehicle or affiliated private fund, such exposures are required to be reported net with the exposures of the reporting fund. If an adviser to an affiliated private fund separately files Form PF, such adviser must exclude such exposures if they have been included in the reporting fund's filing. *See* Question 41.

[357] As discussed in section II.A.2 above, in a modification from the proposal, advisers report trading vehicles on a consolidated basis but in response to certain questions will be required to identify the positions and counterparty exposures that are held through a trading vehicle, which will help differentiate the reporting fund's exposures and risks from those of its trading vehicles.

[358] *See* Question 43.

[359] Under the amendments, however, if an adviser completes the table in Question 42 for a particular counterparty, the adviser is not required to complete the table twice.

[360] *See, e.g.,* Gapper, John and Kaminska, Izabella, Downfall of MF Global—US broker-dealer bankruptcy highlights global reach of eurozone crisis, *Financial Times* (Nov. 2011), *available at https://www.ft.com/content/2882d766-06fb-11e1-90de-00144feabdc0.*

posted insufficient collateral (relative to the amount borrowed).[361]

These amendments are designed to streamline the form by consolidating information currently collected in Question 47 into Question 42, and to improve the quality and comparability of reported information and our ability to integrate the data obtained for analysis with other regulatory data sets by specifying how advisers determine borrowing and counterparty credit exposure.[362] The changes, in conjunction with the new consolidated counterparty exposure table, will also provide a better overall view of hedge funds' borrowing and other financing arrangements and counterparty credit exposure and associated collateral, which will provide critical insight into (1) creditor and counterparty exposure to qualifying hedge funds through synthetic long positions through derivatives, (2) potential gaps in margin received by and posted by qualifying hedge funds and the size of any such gaps, (3) qualifying hedge funds' exposure to a large counterparty failure, and (4) the expected impact on a fund's financing arrangements of a change in margin requirements.

Finally, advisers will no longer be required to report the percentage of the total amount of collateral and other credit support that a fund has posted to counterparties that may be re-hypothecated as currently required in Question 38.[363] We are adopting this change because this reporting is burdensome for advisers, and we have found that the data obtained is generally not reliable because advisers cannot easily collect and report the required information as re-hypothecation commonly occurs from omnibus accounts into which advisers generally do not have visibility.[364]

Some commenters opposed the requirement to provide additional detail regarding counterparty exposure and state that the information would be burdensome and costly to obtain.[365] One commenter recommended limiting the additional counterparty reporting to only a fund's top three counterparties, rather than top five as proposed.[366] For reasons discussed above, disaggregated counterparty exposure is important to systemic risk monitoring efforts. This information will not be significantly burdensome to produce as we understand knowledge of counterparties to be a component of a fund's basic risk management practices. The additional systemic risk benefits described above of receiving data on a fund's five largest counterparties justify the modest additional incremental burden over reporting on the largest three counterparties, as recommended by one commenter.[367]

c. Market Factor Effects

We are adopting, as proposed except as specifically indicated below, amendments to require advisers to qualifying hedge funds to respond on Form PF to all market factors to which their portfolio is directly exposed, rather than allowing advisers to omit a response to any market factor that they do not regularly consider in formal testing in connection with the reporting fund's risk management, as Form PF currently provides.[368] These changes are designed to enhance investor protection efforts and systemic risk assessment by allowing the Commissions and FSOC to track better common market factor sensitivities, as well as correlations and trends in those market factor sensitivities.

We are also changing the stress thresholds to (1) require advisers to report one threshold for each market factor, rather than two as is currently required and (2) include different thresholds for certain market factors to capture stress scenarios that are plausible but still infrequent market moves.[369] Information resulting from stress testing at thresholds in the current form (one low and one high) was not useful because the thresholds are either too frequent (for the lower threshold) or too extreme and may not result in accurate estimates (for the higher threshold). Based on our experience with this information, we do not believe that collecting data at multiple thresholds for each market factor is significantly more meaningful than collecting market factor sensitivity at a single plausible but still infrequent threshold.[370]

The amendments also add a market factor test concerning non-parallel risk-free interest rate movements. It will test hedge fund exposure to changes in the slope of the yield curve, which is currently untested and can be a source of systemic risk when there are sudden interest rate changes. For example, this market factor will provide meaningful information on hedge funds that take complex positions, such as market neutral strategies (*e.g.,* basis trading in particular) and other strategies that employ trades that take advantage of spreads in yield curves coupled with high use of leverage. In a modification from the proposal, we are removing the risk-free interest rates market factor reporting and instead adding an instruction to specify that, with respect to the market factor concerning non-parallel risk-free interest rate movements, the sum of all reported non-parallel risk-free interest rate sensitivities for a given rate movement should total the portfolio's sensitivity to a parallel risk-free interest rate movement of that magnitude to reduce burdens. This modification will reduce the burden on advisers by eliminating a required reporting item and will not diminish data quality because with the added instruction, we can derive the total parallel risk-free rate sensitivity from the non-parallel risk-free interest rate movement market factor.

We are also revising the instructions so advisers will be required to report the long component and short component consistently with market convention, rather than opposite from market convention, as Form PF currently requires, in order to reduce inadvertent mistakes in completing the form.[371]

[361] *See* Form PF Glossary of Terms (definitions of ''cash borrowing entries,'' ''collateral posted entries,'' ''cash lending entries,'' and ''collateral received entries'') for a detailed description of these calculations.

[362] Advisers will be required to report the creditor legal name and LEI, which will aid in the identification of counterparties and facilitate analysis of the interconnectedness of market participants (*e.g.,* Form N–PORT and Form N–CEN already collect LEI for registered investment company counterparties and including LEIs here will facilitate analysis across data sets).

[363] We are redesignating current Question 38 as Question 45.

[364] *See* MFA Letter to Chairman Clayton, Sept. 17, 2018, *available at https://www.managedfunds.org/wp-content/uploads/2020/04/MFA.Form-PF-Recommendations.attachment.final.9.17.18.pdf* (noting the rehypothecated securities are taken out of an omnibus account, which makes reporting for advisers with any certainty difficult).

[365] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter.

[366] MFA Comment Letter II.

[367] *See also infra* section IV.C for further discussion of costs and benefits of the amendments.

[368] *See* Question 47. For market factors that have no direct effect on a reporting fund's portfolio, we instruct filers to enter zero.

[369] For example, advisers currently are required to report the effect of an increase or decrease in equity prices by 5% and by 20%, while under the amendments advisers will only report the effect of a 10% increase or decrease, which is a more plausible but still infrequent scenario.

[370] *See* current Question 42.

[371] We are amending the instructions to provide that ''risk-free interest rates'' include interest rate swap rates in which a fixed rate is exchanged for a risk-free floating rate such as the secured overnight financing rate (''SOFR'') or the sterling overnight index average (''SONIA''). Additionally, we are amending the instructions to specify that (1) for market factors involving interest rates and credit spreads, advisers should separate the effect on its portfolio into long and short components where (i) the long component represents the aggregate result of all positions whose valuation changes in the opposite direction from the market factor under a given stress scenario, and (ii) the short component represents the aggregate result of all positions whose valuation changes in the same direction as the market factor under a given stress scenario, and

We are making two modifications to the proposal. First, we are adding an instruction that when reporting exposures to changes in market factors for indirect positions, an adviser may use reasonable estimates that best represent the exposure to the market factor, consistent with the adviser's internal methodologies and conventions of service providers. This is responsive to commenters that suggested the proposal was unclear in certain questions as to whether an adviser is required to ''look through'' the fund's investments.[372] Second, as discussed further above, we are removing the risk-free interest rates market factor and instead adding an instruction to specify that, with respect to the market factor concerning non-parallel risk-free interest rate movements, the sum of all reported non-parallel risk-free interest rate sensitivities for a given rate movement should total the portfolio's sensitivity to a parallel risk-free interest rate movement of that magnitude. Some commenters opposed the amendments requiring advisers to report on all listed market factors, including any market factors that the adviser does not regularly consider in its stress testing.[373] Currently, the wording of the instructions allows an adviser to omit a response in the event the adviser tested a similar, but not identical, market factor. Accurate and complete reporting of all market factors will provide important systemic risk information. We do not believe this amended requirement will significantly burden advisers because an adviser will only be required to stress test risk factors to which their portfolios are directly exposed and are instructed to report zero for any inapplicable market factors. Further, the modified instruction we are adopting, which permits an adviser to use reasonable estimates that best represent the market factor exposure for indirectly held positions, will alleviate some of the burden of reporting this additional information.

(2) for market factors other than interest rates and credit spreads, advisers should separate the effect on its portfolio into long and short components where (i) the long component represents the aggregate result of all positions whose valuation changes in the same direction as the market factor under a given stress scenario and (ii) the short component represents the aggregate result of all positions whose valuation changes in the opposite direction from the market factor under a given stress scenario. *See* Question 47.

[372] MFA Comment Letter III.

[373] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; Schulte Comment Letter; USCC Comment Letter.

d. Additional Amendments to Section 2

Currency exposure reporting. We are adopting, as proposed except as specifically indicated below, amendments to require qualifying hedge funds to report for each month of the reporting period, in U.S. dollars, (1) the net long value and short value of a fund's currency exposure arising from foreign exchange derivatives and all other assets and liabilities denominated in currencies other than a fund's base currency, and (2) each currency to which the fund has long dollar value or short dollar value exposure equal to or exceeding either (a) five percent of a fund's net asset value or (b) $1 billion.[374] In responding, advisers will be required to include currency exposure obtained indirectly through positions held in other entities (*e.g.,* investment companies, other private funds, commodity pools or other companies, funds, or entities) and may report reasonable estimates if consistent with internal methodologies and conventions of service providers.[375] In a change from the proposal, we are adding an instruction to specify that an adviser may report the data that ''best represents'' the currency exposure from any indirect investments to lessen the reporting burden, as long as such estimates are consistent with the adviser's internal methodologies and conventions of service providers. This currency exposure requirement is designed to provide insight into whether notional currency exposures reported by qualifying hedge funds in Question 33 represent directional exposure or are hedges of equity and/or fixed income positions. This new question will allow us to understand whether a qualifying hedge fund's portfolio is exposed to a given currency, and it will also provide a view into the fund's currency exposure resulting from holdings in foreign securities (*e.g.,* Eurobonds). While current Question 30 already requires advisers to separate currency exposure relating to hedging from other currency, we have found that this data has not been very useful for determining whether a currency position is speculative or a hedge. Additionally, it is important to consider a qualifying hedge fund's currency exposure to identify vulnerabilities to currency fluctuations and market events that affect different countries and regions. Finally, the threshold of either (1) five percent of a fund's net asset value or (2) $1 billion for reporting individual currency exposure is appropriate because it represents, in each prong of the threshold, a material level of portfolio exposure to currency risk at which a deterioration in the value of a particular currency could have a significant negative impact on a fund's investors. We also believe that if multiple large funds have significant exposure to a currency that is rapidly devaluing, this circumstance could raise financial stability concerns, and this reporting will better enable review of this type of situation. More broadly, we also will be able to use the information obtained to identify concentrations in particular currencies and assess the potential impact of market events that affect particular currencies.

[374] *See* Question 33.

[375] This instruction is designed to simplify and reduce the burdens of reporting sub-asset class exposures. Furthermore, advisers are permitted to provide good faith estimates and take currency hedges into account, if consistent with their internal methodologies and information reported internally and to investors.

One commenter discussed the systemic risk concerns present in currency exposures, particularly as demonstrated by recent geopolitical events and resulting currency fluctuations.[376] Other commenters opposed the proposed requirement to report currency exposure stating the information would be of limited value and burdensome to report.[377] Some commenters stated that reporting indirect currency exposure accurately may be difficult because of potential variations in timing or foreign exchange rate sources, which could lead to inaccurate data and false indicators of risk.[378] The modified instruction that we are adopting, which provides that an adviser may report the data that ''best represents'' the currency exposure from any indirect investments, clarifies the reporting requirement and will alleviate some of the reporting burden. More detailed reporting of currency exposure is important for systemic risk purposes. This belief is reinforced by recent experiences of currency fluctuation in the aftermath of geopolitical events that we have observed.

Turnover. We are adopting, as proposed, amendments, to require reporting on a per fund basis on the value of turnover in certain asset classes rather than on an aggregate basis as currently required.[379] Requiring this reporting on a per fund basis will provide more detailed information to us and FSOC while at the same time

[376] Fact Coalition Comment Letter.

[377] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; USCC Comment Letter.

[378] AIMA/ACC Comment Letter; MFA Comment Letter II.

[379] Question 34. In connection with amendments, reporting on the value of turnover in certain asset classes and the geographical breakdown of investments is moved from section 2a to section 2.

simplifying reporting for advisers. We understand that advisers do not currently aggregate turnover related information among funds. Aggregating solely for Form PF reporting is particularly burdensome as the required data is typically on separate reporting systems and advisers must ''roll-up'' data from these sources to report on the form.

We are also adding, as proposed, new categories for turnover reporting that disaggregate combined categories and better capture turnover of potentially relevant securities, such as various types of derivatives (*e.g.,* listed equity, interest rate, foreign exchange), which will help support analysis of hedge fund market activity.[380] Furthermore, we are adding a new consolidated foreign exchange and currency swaps category and making other changes, as proposed.[381] During the March 2020 COVID–19-related market turmoil, FSOC sought to evaluate the role hedge funds played in disruptions in the U.S. treasury market by unwinding cash-futures basis trade positions and taking advantage of the near-arbitrage between cash and futures prices of U.S. Treasury securities.[382] Because the current requirement regarding turnover reporting on U.S. Treasury securities is highly aggregated, the SEC staff, during retrospective analyses on the March 2020 market events, was unable to obtain a complete picture of activity relating to long treasuries and treasury futures. Given the significant size of hedge funds' exposures to certain derivative products, it is important to gain more insight into trading activities with respect to these financial instruments to better enable the Commissions and FSOC to assess and monitor the activity of qualifying hedge funds for systemic risk implications.[383] Expanded reporting on turnover also will provide better information for assessing trading frequency in lieu of requiring advisers to report what percentage of their hedge funds' net asset value is managed using high-frequency trading strategies.[384]

Some commenters opposed the proposed requirement for disaggregated and more detailed reporting of turnover stating that such information is of limited value and burdensome to report.[385] As discussed above, we continue to believe that turnover information is related to systemic risk and observing turnover data in particular categories can help identify affected funds and identify possible contagion risk. Moreover, the adopted requirement of disaggregated reporting is less burdensome than the existing reporting of turnover, which requires advisers to aggregate data that we understand they collect on a fund-level basis.

Country and industry exposure. We are adopting, as proposed except as specifically indicated below, amendments to require advisers to report all countries (by ISO country code [386]) to which a reporting fund has exposure equal to or exceeding either (1) five percent of its net asset value or (2) $1 billion, and to report the dollar value of long exposure and the dollar value of short exposure in U.S. dollars, for each monthly period to improve data comparability across funds.[387] In a change from the proposal, we are adding an instruction to specify that advisers may report the data that best represents the country and industry exposure from any indirect investments and is consistent with the advisers' internal methodologies and conventions of services providers to lessen the reporting burden. Under the current approach, only certain regions were identified, and these regions were not uniformly defined, which resulted in data that was not consistent.[388] In addition, at times we have needed to identify countries of interest not on this list. As such, we are adopting amendments to replace the country of interest and regional reporting with this new country level information. Finally, the threshold of either (1) five percent of net asset value or (2) $1 billion is appropriate because it represents a material level of portfolio exposure to risk relating to individual countries and geographic regions and is a level that could significantly impact a fund and its investors if, for example, there are currency fluctuations or geopolitical instability. Furthermore, the data obtained will allow for identification of industry concentrations in particular countries and/or regions and help assess the potential impact of market events on these geographic segments. The five percent threshold level constitutes a reasonable shock to a fund's net asset value. For example, to the extent there is a market-wide event, a worst-case scenario would be for long positions to lose their full value, in this shock case at least five percent. Furthermore, and particularly for funds without a benchmark, five percent is often evaluated for industry, individual position, and country risk, and is a common and easy to measure threshold. With respect to the $1 billion threshold, it constitutes sufficiently large nominal value exposure from a risk perspective.

We are also adding a new question that requires advisers to provide information about each industry to which a reporting fund has exposure equal to or exceeding either (1) five percent of its net asset value or (2) $1 billion, as proposed.[389] Advisers are required to report, for each monthly period, the long dollar value and short dollar value of a reporting fund's exposure by industry based on the NAICS [390] code of the underlying exposure.[391] The purpose of this new question is to collect information that will provide insight into hedge funds' industry exposures in a standardized way to allow for comparability among funds and meaningful aggregation of data to assess overall industry-specific concentrations. Further, the threshold of either (1) five percent of net asset value or (2) $1 billion is appropriate because it represents a material level of portfolio exposure to risk relating to individual

[380] We are also breaking out some categories by futures, swaps, and options as different types of derivatives have different risk profiles and implications for systemic risk, and to add a category for ''other derivative instrument types'' so that all derivatives are reported.

[381] We are revising the asset class categories to require advisers to report turnover in derivatives separately from turnover in physical holdings in Question 34 and are making other conforming changes to reflect changes to defined terms in the Form PF Glossary of Terms.

[382] *See* U.S. Credit Markets Interconnectedness and the Effects of the COVID–19 Economic Shock, U.S. Securities Exchange Commission, Oct. 2020, *available at https://www.sec.gov/files/US-Credit-Markets_COVID-19_Report.pdf. See also* Financial Stability Oversight Council 2021 Annual Report, *available at https://home.treasury.gov/system/files/261/FSOC2021AnnualReport.pdf.*

[383] As of the end of first quarter of 2023, interest rate derivatives currently make up approximately 30% of gross notional exposure (GNE) reported on Form PF, while foreign exchange derivatives make up approximately 13% of GNE. Additionally, commodity, credit, and other derivatives when combined make up 5% of GNE or over $1.3 trillion. *See* Private Fund Statistics Q1 2023, *supra* footnote 5.

[384] We are removing current Question 21 as it is redundant in light of the adopted expanded turnover reporting.

[385] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; USCC Comment Letter.

[386] This is similar to reporting on Form N–PORT and will improve the comparability of data between Form PF and Form N–PORT.

[387] Question 35. In connection with the amendments, reporting on geographical breakdown of investments has moved from current section 2a to section 2.

[388] Currently, consistent with staff Form PF Frequently Asked Questions 28.1 and 28.2, advisers are permitted to report geographical exposure based on internal methods and indicate in Question 4 if methods did not reflect risk and economic exposure. *See* Form PF Frequently Asked Questions, *supra* footnote 162.

[389] *See* Question 36.

[390] North American Industry Classification System.

[391] *See* United States Census Bureau, North American Industry Classification System, *available at https://www.census.gov/naics/.*

industries, and is a level that could significantly impact a fund and its investors if, for example, there are market or geopolitical events that affect performance by a particular industry, such as the burst of the ''tech bubble'' in the early 2000s or COVID–19's impact on airline, accommodation and food service industries. Furthermore, the data obtained will allow for identification of industry concentrations and help assess the potential impact of market events on industries. While we considered a lower threshold, we continue to believe that the adopted threshold strikes an appropriate balance between identifying significant industry exposure and the burdens of reporting this information on Form PF. This information will be useful to the Commissions and FSOC in monitoring systemic risk, particularly if multiple funds have significant concentrations in industries that are experiencing periods of stress or disruption.

When responding to these questions about country and industry exposure, advisers are required to include exposure obtained indirectly though positions held in other entities (*e.g.,* investment companies, other private funds, commodity pools or other company, funds, or entities). Without this requirement, a fund's exposure to geographic regions and industries could be obscured and hinder the Commissions' and FSOC's ability to assess risks and the potential impact of events and trends that affect a particular industry or geographic region, both of which could have implications for investors. While advisers typically maintain this information, the instructions to these questions seek to minimize filer burdens by permitting advisers to report reasonable estimates if such reporting is consistent with internal methodologies and information reported internally and to investors.

Some commenters opposed the proposed requirements for more granular reporting, including amendments to require more detailed reporting on country and industry exposure, stating that such information would be of limited value for systemic risk analysis and burdensome to report.[392] Another commenter, however, discussed how geopolitical instability and industry disruptions can contribute to systemic risk.[393] For reasons discussed above, country and industry exposure reporting is important for systemic risk, and exposures in excess of five percent of a fund's net asset value could be significant enough to pose contagion risks. In a modification from the proposal, we are adding an instruction to provide that an adviser is permitted to report reasonable estimates of a fund's country and industry exposure, provided such reporting is consistent with internal methodologies and information reported internally and to investors, which is intended to lessen the burden on advisers, while allowing us to continue to receive this reporting on country and industry exposure.

One commenter stated that requiring advisers to report industry exposure by NAICS is burdensome because funds may not currently collect this data and it may be costly to obtain.[394] We disagree that NAICS information is significantly burdensome to obtain and report. NAICS codes are publicly available and is the standard used by certain Federal agencies for classifying entities by industry.[395]

Central clearing counterparty (CCP) reporting. We are adopting, as proposed except as specifically indicated below, amendments to require advisers to identify each CCP or other third party holding collateral posted by a qualifying hedge fund in respect of cleared exposures (including tri-party repo) equal to or exceeding either (1) five percent of a reporting fund's net asset value or (2) $1 billion.[396] The new question excludes counterparties already reported in Question 42 and Question 43,[397] and requires advisers to provide information on: (1) the legal name of the CCP or third party; (2) LEI (if available); (3) whether the CCP or third party is affiliated with a major financial institution; (4) the reporting fund's posted margin (in U.S. dollars); and (5) the reporting fund's net exposure (in U.S. dollars), as proposed. In a modification from the proposal, we are also requiring advisers to provide information on the legal name of the collateral owner and the collateral owner LEI. This additional identifying information will allow us to understand the reporting fund's exposure by differentiating exposures of the reporting fund from exposures of other reporting entities. For example, as discussed more fully above in section II.A.2, advisers report on trading vehicles on a consolidated basis with the reporting fund, and without identifying information, we would be unable to differentiate a reporting fund's counterparty risk exposure from that of its trading vehicle.

We are adopting this new question based on our experience with Form PF since adoption as we have found data gaps with respect to identifying qualifying hedge fund exposures to CCPs and other third parties that hold collateral in connection with cleared exposures. Furthermore, we understand that (1) many large hedge fund advisers already track margin posted for cleared exposures because margin requirements at any given time may well exceed the clearinghouse's exposure to a fund and therefore are an important credit risk exposure metric for a fund, and (2) that CCP recovery, resiliency and resolution also are current concerns for some advisers.[398] Given these factors, the burden of this new question is justified by valuable insight the data obtained will provide into an area that could have significant implications from a systemic risk perspective. Additionally, we have chosen a reporting threshold of equal to or exceeding either (1) five percent of net asset value or (2) $1 billion to be consistent with the thresholds for other counterparty exposure questions,[399] as a qualifying hedge fund is similarly exposed where a third party holds collateral irrespective of whether the third party is a CCP or other counterparty. We are also removing current Question 39, which required information about transactions cleared directly through a CCP, as the information collected is duplicative of information already collected in current Question 24 (redesignated Question 29).

One commenter recommended that exposures to CCPs should be reported on an aggregate basis, rather than on an individual CCP basis, because some advisers track these exposures on an aggregate basis and the Commissions have not explained why reporting on an aggregate basis is not sufficient and recommended clarifying whether the instruction in Question 43 to report information for counterparties that are CCPs or other third parties holding collateral in respect of ''cleared exposures'' is meant to refer to ''centrally cleared exposures.'' [400] The references to cleared exposures in the instructions to Question 43 are meant to

[392] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; USCC Comment Letter.

[393] Fact Coalition Comment Letter.

[394] MFA Comment Letter II.

[395] *See, e.g.,* SBA Small Business Size Regulations, 13 CFR 121.101 (2023).

[396] *See* Question 44.

[397] *See* discussion at section II.C.2.b of this Release.

[398] *See* ''A Path Forward For CCP Resilience, Recovery, And Resolution,'' Mar. 10, 2020, *available at https://www.blackrock.com/corporate/literature/whitepaper/path-forward-for-ccp-resilience-recovery-and-resolution.pdf. See also* J.P. Morgan Press Release, Mar. 10, 2020, *available at https://www.jpmorgan.com/solutions/cib/markets/a-path-forward-for-ccp-resilience-recovery-and-resolution.*

[399] *See* discussion at section II.C.2.b of this Release.

[400] MFA Comment Letter II.

include centrally cleared exposures, as well as other cleared exposures. Receiving data on which individual CCPs are used for centrally cleared positions is important for understanding systemic risk resulting from a concentrated use of the same CCPs among different funds. Further, a CCP default may result in delayed receipt of funds that can create spillover effects at funds, particularly highly leveraged funds, that raise systemic risk and investor protection concerns. While the clearing system is highly risk reducing and transparent, default of a fund, or of a clearing member, could nonetheless cause temporary dislocations that can become significant at critical times. Transparency at this level is important in Form PF and is aligned with funds' own need to be aware of exposures to individual clearing members. For these reasons, it is appropriate to require this reporting as proposed. This commenter also argued that the requirement to report collateral posted by a fund to meet exchange requirements and separately report additional collateral collected by the prime broker would be difficult for advisers that do not actively monitor exchange margin requirements distinctively from prime broker margin requirements.[401] We disagree that this information would be difficult for advisers to report because the instructions to Question 42 specify a simplified method of how to report such blended margin arrangements, including where collateral is not disaggregated.[402] The commenter recommended that the Commissions instead require prime brokers to provide this information in standard form and permit advisers to rely on information provided by their prime broker.[403] It is important for advisers to report this information aggregated for the reporting fund because individualized reporting from each prime broker may obscure the fund's counterparty risk. For example, a fund that has arrangements with multiple prime brokers may have a particular counterparty exposure across multiple prime brokerage arrangements, which may be obscured by separate reporting for each prime broker. Further, it is important for a reporting fund to understand its own counterparty risk, and we understand advisers monitor levels of counterparty concentration for risk management purposes. Therefore, we believe it is appropriate for advisers to report this information on Form PF with other exposure reporting. Individual reporting on CCPs is important because aggregated reporting would not provide sufficiently detailed information to allow us to identify potential risks. For example, in the event of a particular counterparty failure, we would be unable to accurately localize a fund's risk exposure to that counterparty.

Risk metrics. We are adopting, as proposed, amendments to eliminate the requirement that an adviser indicate whether there are risk metrics other than, or in addition to, Value at Risk (''VaR'') that the adviser considers important to managing a reporting fund's risks.[404] Advisers generally have not reported detailed information in response to this requirement. Currently, about 55 percent of advisers to qualifying hedge funds (representing about 75 percent of the aggregate gross asset value of qualifying hedge funds) report using VaR or market factor changes in managing their hedge funds.[405] Instead, advisers will be required to provide additional information about a reporting fund's portfolio risk profile, investment performance by strategy, and volatility of returns and drawdowns.[406] This amendment will expand the amount of data collected by collecting risk data in circumstances where advisers do not use VaR or market factor changes, and thus will provide insight across all (rather than only some) qualifying hedge funds. This new information will provide uniform and consistently reported risk information that will enhance our ability to monitor and assess investment risks of qualifying hedge funds to gauge systemic risk. In particular, volatility of returns and drawdown data is a simple measure of risk that enables us to monitor risk-adjusted returns, changes in volatility and thereby risk profiles. We did not receive specific comment on this amendment.

Investment performance by strategy. We are adopting, in a modification from the proposal, amendments to require to qualifying hedge funds that indicate more than one investment strategy for a fund in Question 25 to report monthly gross investment performance by strategy if the adviser reports this data for such fund, whether to current and prospective investors, counterparties, or otherwise, rather than if the adviser ''calculates and reports'' such information to third parties, as proposed.[407] Advisers will not be required to respond to this question if the adviser reports performance for the fund as an internal rate of return, as proposed. This question is designed to integrate Form PF hedge fund data with the FRB's reporting on Financial Accounts of the United States, which the FRB uses to track the sources and uses of funds by sector, and which are a component of a system of macroeconomic accounts including the National Income and Product accounts and balance of payments accounts, all of which serve as a comprehensive set of information on the economy's performance. We also believe that this information will be helpful to the Commissions' and FSOC's monitoring and analysis of strategy-specific systemic risk in the hedge fund industry. One commenter recommended that the requirement be limited to reporting on investment strategies that the fund reports to third parties.[408] This commenter also stated that the proposed instructions were not clear how an adviser should respond if it does not report such information to third parties. After considering comments, in a change from the proposal, advisers will be required to respond to this question only if they actually report investment performance to third parties; thus, advisers will not be required to respond to this question if they only calculate (but do not report) such information. This change will allow us to continue to receive strategy performance information that is reported to third parties while reducing the burden on

[401] *Id.*

[402] Specifically, Question 42(a)(iii) instructs as follows: ''check this box if one or more prime brokerage agreements provide for cross-margining of derivatives and secured financing transactions. If you have checked this box, and collateral does not clearly pertain to secured financing vs. derivatives transactions, report exposures and collateral as follows: . . . enter any additional collateral gathered by the prime broker under a cross margining agreement on lines (iii)(B), (C), (D), and (E).

[403] MFA Comment Letter II.

[404] *See* current Question 41.

[405] *See* Private Funds Statistics Q1 2023 (Table 58/59). Current Question 40 (redesignated Question 46) requires advisers to report certain risk data if the adviser regularly calculates VaR of the reporting fund. Current Question 42 (redesignated Question 47) requires advisers, for specific market factors, to determine the effect of specified changes on a reporting fund's portfolio but permits advisers to omit a response to any market factor that they do not regularly consider in formal testing in connection with a reporting fund's risk management.

[406] *See* Question 49 (investment performance breakdown by strategy), and Question 23(c) (volatility of returns and drawdown reporting). *See* discussion at section II.B.2 of this Release. We are also revising the title of Item C. of section 2 to ''Reporting fund risk metrics and performance'' to reflect the addition of new questions on performance to this section of the form.

[407] Question 49. The strategies in Question 49 are based on the strategies included in the drop-down menu in Question 25 (we are also including a drop-down menu for the strategy categories in Question 25, to better reflect our understanding of hedge fund strategies and to improve data quality and comparability). *See* discussion at section II.B.3 of this Release.

[408] MFA Comment Letter II.

advisers. We understand that advisers may frequently calculate strategy performance for purposes other than reporting performance to third parties and that requiring reporting of each such calculation may be of more limited value and may be burdensome to report.

Portfolio Correlation. In a change from the proposal, we are not adopting a proposed question on portfolio correlation to collect data on the effects of a breakdown in correlation. We received several comments stating that the proposed portfolio correlation question would impose significant burdens on advisers because portfolio correlation is not a commonly calculated risk measurement and can be complex to calculate.[409] One commenter recommended only requiring an adviser to report portfolio correlation if correlation is a risk analysis metric that the adviser reports to its investors.[410] In light of comments we received, we are persuaded that the complexity and corresponding increased burden associated with the proposed portfolio correlation question would be significant. The new and modified questions we are adopting in this Release will also enhance our leverage monitoring efforts and enhance our data insights on counterparty exposures without including the proposed portfolio correlation question.

Portfolio Liquidity. We are adopting, as proposed, amendments to require advisers to include cash and cash equivalents when reporting portfolio liquidity, rather than excluding them, as the question currently provides.[411] We understand that reporting funds typically include cash and cash equivalents when analyzing their portfolio liquidity. This change will improve data quality by reducing inadvertent errors that result from requiring advisers to report in a way that is different from how they may report internally. This change is more reflective of industry practice, and it is preferable to receive reported data in a format that reflects how advisers typically analyze portfolio liquidity.

We are also amending the form's instructions to allow advisers to assign each investment to more than one period, rather than directing advisers to assign each investment to only one period, as Question 32 currently provides. We understand that directing advisers to assign an investment to only one period may make a reporting fund's portfolio appear less liquid than it is because it would not reflect that reporting funds may divide up sales in different periods (*e.g.,* a reporting fund could sell off a portion in the first time period and sell of the remainder in subsequent time periods). Therefore, this change is designed to reflect the liquidity of a reporting fund's portfolio more accurately.

While advisers will continue to be able to rely on their own methodologies to report portfolio liquidity, we are adding an instruction explaining that estimates must be based on a methodology that takes into account changes in portfolio composition, position size, and market conditions over time. Based on experience with the form, we have found that some advisers have used static methodologies that do not consider portfolio composition and position size relative to the market, and therefore do not reflect a reasoned view about when positions could be liquidated at or near carrying value. Therefore, this change will continue to allow advisers to use their own methodologies but improve data quality to ensure that the methodologies generate reporting that reflects a reasonable view of portfolio liquidity in light of changes in portfolio composition and size, and market conditions, over time.

One commenter stated that portfolio liquidity is a metric that may create misleading impressions when assessed on a disaggregated fund by fund basis.[412] As discussed more fully above in section II.A of the Release, disaggregated reporting, rather than being misleading, allows for a clearer understanding of the reporting fund's structure, including its portfolio liquidity, because we can observe liquidity on a fund by fund basis while continuing to allow aggregation of data across the fund structure for the broader context. This commenter also stated the proposed instruction regarding how to report the percentage of fund's net asset value that may be liquidated within each period if an investment is assigned to more than one period was unclear. In consideration of this comment, we are adding an instruction to specify that if an investment is assigned to more than one period, the adviser should reflect the percentage of NAV that might be liquidated within each period, rather than the percentage of NAV that the entire investment represents.[413] The same commenter stated that we should clarify the meaning of the proposed instruction that estimates must be based on a methodology that takes into account changes in portfolio composition, position size, and market conditions over time. To address this comment, we are also revising the instructions to specify that, for example, estimates would change if the portfolio invests in more or less liquid assets, if/when the portfolio investments grow to a size relative to the liquidity of the markets in which it invests that requires more time to liquidate, and if liquidity characteristics change measurably and meaningfully for the assets in which the portfolio invests.[414] This commenter also recommended that the total portfolio liquidity should not be expressed as a percentage of a fund's net asset value, in light of the instruction that suggests that the total may not add up to 100 percent.[415] The instruction that the total percentages should add up to approximately 100 percent is appropriate because we recognize that rounding differences may result in a calculated total percentage that does not equal 100 percent. We continue to believe that portfolio liquidity should be expressed as a percentage of net asset value because net asset value is also the unit in which redemptions take place and would allow calculations in value, if needed.

Finally, to facilitate more accurate reporting, collect better data, and reduce filer errors, we are amending the table to be included in new Question 37 to reflect that information should be reported as a percentage of NAV consistent with SEC staff Form PF Frequently Asked Questions.[416] We did not receive specific comment on this amendment.

Financing and Investor Liquidity. Current Question 46 is designed to show the extent to which financing may become rapidly unavailable for qualifying hedge funds.[417] We are adopting, as proposed, amendments to current Question 46 to improve data quality thereby supporting more effective systemic risk analysis.[418] Advisers will be required to provide the dollar amount of financing that is available to the reporting fund, including financing that is available but not used, by the following types: (1) ''unsecured borrowing,'' (2) ''secured borrowing'' via prime brokerage, (3) secured borrowing via reverse repo, and

[409] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II.

[410] AIMA/ACC Comment Letter.

[411] *See* Question 37.

[412] MFA Comment Letter II.

[413] Question 37.

[414] *Id.*

[415] MFA Comment Letter II. *See also* Question 37.

[416] *See* Form PF Frequently Asked Questions, *supra* footnote 162, Question 32.3.

[417] *See* 2011 Form PF Adopting Release, *supra* footnote 4, at text accompanying n.281.

[418] We redesignated current Question 46 as Question 50.

(4) other secured borrowings.[419] Currently, the Commissions and FSOC infer this data from this question and current Question 43 (concerning the reporting fund's borrowings).[420] However, these inferences may not be accurate given the number of assumptions that currently go into making such inferences. This information will help us understand the extent to which a fund's financing could be rapidly withdrawn and not replaced. We did not receive specific comment on this amendment. Current Question 50, which we have redesignated as Question 53, requires an adviser to report the percentage of the fund's net asset value that is subject to suspensions and restrictions on withdrawals/redemptions for various time periods. In a modification from the proposal, we are amending Question 53 to instruct the adviser to make a good faith determination of the withdrawal and redemption restrictions that would likely be triggered during significant market stress conditions. This additional instruction addresses commenters' concerns by reducing the reporting burden for advisers that advise funds with varying redemption and withdrawal rights and improve data quality.[421]

Definition of ''Hedge Fund.'' We requested comment on whether we should amend the definition of ''hedge fund'' as it is defined in the Form PF Glossary of Terms. After considering comments, we are not adopting any amendments to the existing definition of ''hedge fund'' at this time. Certain commenters generally supported revising the definition of ''hedge fund'' to remove deemed hedge funds (*i.e.,* a private fund reported as a ''hedge fund'' as Form PF directs because the fund's governing documents permit the fund to engage in certain borrowing and short selling (even though it did not do so at any time in the past)).[422] These commenters supported revising the definition of ''hedge fund'' to exclude private funds that have an ability to use leverage or engage in shorting but do not do so in the ordinary course of business and that the market does not generally consider to be hedge funds. Some commenters recommended adopting a *de minimis* test, which would exclude any private fund from the definition that has not recently engaged in shorting or borrowing activity within a specified period, such as within the last 12 months, or has not engaged in these activities in excess of a specified amount, such as greater than 0.5% or 1% of the fund's net asset value.[423] One commenter recommended an exclusion for any private fund whose borrowing activities are only related to real estate.[424] Another commenter recommended including a rebuttable presumption in the definition that a private fund that holds itself out as a hedge fund is a hedge fund, while a private equity fund that holds itself out as pursuing a private equity strategy is not a hedge fund, similar to the venture capital exemption under the Advisers Act.[425] Another commenter recommended specifying in the definition that only private funds that provide redemption rights in the ordinary course can be classified as hedge funds.[426] One commenter recommended revising the definition to remove the default treatment of commodity pools as hedge funds.[427]

The existing definition is designed to include any private fund having any one of three common characteristics of a hedge fund: (1) a performance fee that takes into account market value (instead of only realized gains); (2) leverage; or (3) short selling. We believe that any private fund that has one or more of these characteristics is an appropriate subject for the more detailed level of reporting that hedge funds are subject to on Form PF because the questions that hedge fund advisers are required to complete focus on these activities which bring funds within the ''hedge fund'' definition. Without classifying these funds as hedge funds for the purpose of Form PF, we would not receive important reporting on these activities which may contribute to systemic risk, particularly in the event of a fund that has the ability to engage in borrowing or short selling activities. Incorporating any carveouts in the definition, such as the recommended *de minimis* exception for borrowing or short selling, could cause further data mismatches and increase the burden on advisers because certain funds could be required to fluctuate between different reporting categories in different reporting periods depending on the fund's practices in any given period. In our experience, such an exclusion would eliminate only a limited number of private funds from the reporting category. We also believe that short selling and borrowing are important distinguishing characteristics of hedge funds and providing any exception for these activities, including a *de minimis* one, could have a significant, negative effect on reporting. Therefore, we do not believe that including responses from these private funds in the reporting information from hedge fund advisers impairs our data quality. We also believe adopting a rebuttable presumption is not appropriate because it would increase burdens on advisers by effectively requiring an adviser to produce evidence of its filing category. Further, this approach would effectively allow an adviser to determine whether it reports the additional information that hedge fund advisers are required to report on Form PF, which would diminish the quality and value of data collected on Form PF. Additionally, as it relates to the treatment of commodity pools as hedge funds for reporting purposes, such treatment further aligns the consistency of questions asked across these entities, both on this Form PF, as well as on the CFTC's Form CPO–PQR.

D. Amendments To Enhance Data Quality

We are also adopting, as proposed except as specifically provided below, several amendments to the instructions to Form PF to enhance data quality.[428] Specifically, we are adopting the following changes:

Reporting of percentages. For questions that require information to be expressed as a percentage, we are adopting, as proposed, an amendment to

[419] Form PF defines ''unsecured borrowing'' as obligations for borrowed money in respect of which the borrower has not posted collateral or other credit support. Form PF defines ''secured borrowing'' as obligations for borrowed money in respect of which the borrower has posted collateral or other credit support. For purposes of this definition, reverse repos are secured borrowings. *See* Form PF Glossary of Terms. These categories are designed to be consistent with borrowing categories that qualifying hedge funds will report on the new counterparty exposure table.

[420] Current Question 43 collects data on the reporting fund's borrowing by type (*e.g.,* unsecured, and secured by type, *i.e.,* prime broker, reverse repo or other), while current Question 46 only collects a total amount of financing available, both used and unused, with no breakdown by type of financing.

[421] As discussed more fully above in section II.B.2 of this Release, some commenters stated that, in the context of proposed Question 10, the proposed amendments should permit reporting of multiple types of redemption and withdrawal rights. *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter; USCC Comment Letter.

[422] *See, e.g.,* AIC Comment Letter I; CFA Institute Comment Letter; Ropes & Gray Comment Letter; Schulte Comment Letter; SIFMA Comment Letter.

[423] *See* AIC Comment Letter I; Ropes & Gray Comment Letter.

[424] *See* SIFMA Comment Letter.

[425] *See* Ropes & Gray Comment Letter. 17 CFR 275.203(l)–1. *See* Exemptions for Advisers to Venture Capital Funds, Private Fund Advisers with Less than $150 Million in Assets Under Management, and Foreign Private Advisers, Advisers Act Release No. 3222 (June 22, 2011) [76 FR 39646 (July 6, 2011)].

[426] *See* CFA Institute Comment Letter.

[427] *See* MFA Comment Letter II.

[428] Instruction 15 (provides guidelines for advisers in responding to questions on Form PF relying on their own methodology).

require that percentages be rounded to the nearest one hundredth of one percent rather than rounded to the nearest whole percent. This additional level of precision is important, especially for questions where it is common for filers to report low percentage values (*e.g.,* risk metric questions such as Question 40 and Question 42) to avoid situations where advisers round to zero and no data is reported, potentially obscuring small changes that may be meaningful from a risk analysis or stress testing perspective. One commenter stated that the requirement to report information expressed as a percentage to the nearest one hundredth of one percent will significantly increase the costs and additional burdens for reporting advisers.[429] This commenter also stated that, if the Commissions provide a basis for requiring additional granularity, the Commissions should amend the instruction to require reporting rounded to the nearest one tenth of one percent, rather than one hundredth of one percent.

Percentages rounded to the nearest one hundredth of one percent will allow the Commissions to obtain and analyze more precise information that may otherwise be obscured. For example, one one-hundredth of one percent can represent a meaningful dollar amount depending on the size of the private fund. And, while we recognize that this may not be the case for smaller funds, when such amounts are taken together for a large group of smaller funds, the aggregate amount across the fund group can represent a meaningful dollar amount for data analysis purposes. Furthermore, as noted above, this level of detail is particularly important for questions where it is common for filers to report low percentage values to avoid situations where advisers round to zero and no data is reported. Finally, we understand that many advisers already use electronic spreadsheet programs and other tools to generate percentages and assist with rounding, which should limit the incremental burdens and costs on advisers. While we considered less granular reporting, such as rounding to the nearest one tenth of one percent, the adopted threshold strikes an appropriate balance between enhancing Form PF data quality and the burdens and costs of reporting this information on Form PF.

Value of investment positions and counterparty exposures. We are amending, as proposed, the instructions to specify how private fund advisers determine the value of investment positions (including derivatives) and counterparty exposures. We are adopting amendments to require derivatives trades to be reported independently on a gross basis, consistent with derivatives reporting on Form N–PORT.[430] We are also amending the instruction that for all positions reported on Form PF, to not include as ''closed-out'' a position if the position is closed out with the same counterparty and results in no credit or market exposure to the fund, making the approach on Form PF with respect to closed out positions consistent with rule 18f–4 of the Investment Company Act and our understanding of filers' current practices.[431] We did not receive specific comment on these amendments. These changes will provide a more consistent presentation of reported information on investment and counterparty exposures to support more accurate aggregation and comparisons among private funds by us and FSOC in assessing systemic risk.

Reporting of long and short positions. We are amending, as proposed, the instructions regarding the reporting of long and short positions on Form PF to improve the accuracy and consistency of reported data used for systemic risk analysis. The amended instructions specify that if a question requires the adviser to distinguish long positions from short positions, the adviser should classify positions based on the following: (1) a long position experiences a gain when the value of the market factor to which it relates increases (and/or the yield of that factor decreases), and (2) a short position experiences a loss when the value of the market factor to which it relates increases (and/or the yield of that factor decreases). Although some commenters supported the proposed amendments to require advisers to report their long and short holdings on a disaggregated basis [432] and other commenters opposed the requirements for more detailed disclosure of holdings,[433] we did not receive specific comment on the proposed change to the instructions defining long and short positions. The amended instructions will improve the data quality and comparability used for systemic risk analysis.

Calculating certain derivative values. We are amending, with a modification from the proposal, the instruction to provide that, (1) for calculating the value of interest rate derivatives, ''value'' means the 10-year bond equivalent, and (2) for calculating the value of options, ''value'' means the delta adjusted notional value (expressed as a 10-year bond equivalent for options that are interest rate derivatives).[434] In a change from the proposal, the amended instructions provide that the value should be expressed in U.S. dollars, rather than the base currency of the reporting fund, to maintain consistent currency reporting throughout Form PF. One commenter stated that the definition of ''10-year bond equivalent'' specifies the expression of the value in the fund's base currency, which could result in requiring multiple currency conversions for any transactions not in the fund's base currency.[435] We are revising the ''10-year bond equivalent'' definition to reference U.S. dollars, rather than the fund's base currency. We are making this change because it is important for metrics to be reported in a common currency for data quality and comparability purposes. The amended instruction also provides that in determining the value of these derivatives, advisers should not net long and short positions or offset trades but should exclude closed-out positions that are closed out with the same counterparty provided that there is no credit or market exposure to the fund. The amendments are designed to provide more consistent reporting by advisers, which will help support more accurate aggregation of data, better comparisons among funds, and a more accurate picture for purposes of assessing systemic risk.[436]

Currency Conversions for Reporting in U.S. Dollars. We are amending, as proposed, Instruction 15 to specify that if a question requests a monetary value, advisers should provide the information

[429] MFA Comment Letter II.

[430] Specifically, Instruction 15 requires that if a question in Form PF requests information regarding a ''position'' or ''positions,'' advisers must treat legs of a transaction even if offsetting or partially offsetting, or even if entered into with the same counterparty under the same master agreement as two separate positions, even if reported internally as part of a larger transaction. *See also* instructions to N–PORT, General Instruction G.

[431] *See* Use of Derivatives by Registered Investment Companies and Business Development Companies, Release No. 34084 (Nov. 2, 2020) [85 FR 83162, 83210 (Dec. 21, 2020)]. *See also* Form PF Frequently Asked Questions, *supra* footnote 162, Question 44.1.

[432] *See* AFREF Comment Letter I; Better Markets Comment Letter. *See supra* section II.C.2.a.

[433] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter. *See supra* section II.C.2.a.

[434] *See* Form PF Glossary of Terms (definition of ''10-year bond equivalent'' specifies the 10-year zero coupon bond equivalent).

[435] AIMA/ACC Comment Letter.

[436] This is consistent with staff Form PF Frequently Asked Questions, *see, e.g., supra* footnote 162, Questions 24.3 and 26.1.

in U.S. dollars as of the data reporting date or other requested date (as applicable) and use a foreign exchange rate for the applicable date. We are also amending Instruction 15 to provide that if a question requests a monetary value for transactional data that covers a reporting period, advisers should provide the information in U.S. dollars, rounded to the nearest thousand, using foreign exchange rates as of the dates of any transactions to convert local currency values to U.S. dollars.[437]

One commenter stated that private funds should be required to report their holdings in the fund's base currency, rather than convert to U.S. dollars, to allow for assessment of the extent of a fund's currency risk exposure.[438] We agree that currency exposure reporting is important for understanding a fund's overall risk exposure and for systemic risk analysis and, as discussed more fully in section II.C above, we are adopting other amendments to Form PF that require large hedge fund advisers to report additional data on the fund's currency risk exposure.[439] Regarding currency reporting, however, it is important for data comparability for advisers to report in a common currency, rather than in a fund's base currency, and for an adviser to determine foreign exchange rates consistent with its valuation policies because reporting in a common currency allows the Commissions to evaluate aggregate data, such as exposures, more readily. One commenter recommended specifying a required time of day and methodology for determining the applicable foreign exchange rate to avoid inconsistent data.[440] Although specifying a time of day and methodology could improve data comparability, this would distort values reported on Form PF from what advisers calculate and report to their investors because these values are similar to prices on any other portfolio investment. For a foreign exchange rate, the adviser is valuing a currency, but generally should be doing so using the same source, time of day, or other methodology for capturing foreign exchange rates as is defined in the adviser's or fund's valuation policy. It is preferable for advisers to report values using the foreign exchange rate practices they use internally and to report to their investors.

[437] See Instruction 15.

[438] AFREF Comment Letter I.

[439] *See* Question 33.

[440] AIMA/ACC Comment Letter.

E. Additional Amendments

We are adopting, as proposed except as indicated below, several additional amendments to the general instructions to Form PF. We are adopting an amendment to Instruction 14 to allow advisers to request a temporary hardship exemption electronically to make it easier to submit a temporary hardship exemption.[441] We are also adopting an amendment to 17 CFR 275.204(b)–1(f) under the Advisers Act, that for purposes of determining the date on which a temporary hardship exemption is filed, ''filed'' means the earlier of the date the request is postmarked or the date it is received by the Commission.[442] We are adopting the latter change to assist advisers with determining what constitutes a ''filed'' temporary hardship exemption in the context of the requirement that the request be filed no later than one business day after a filer's electronic Form PF filing was due as required under Instruction 14. We did not receive comments on these proposed amendments.

Additionally, we are adopting, as proposed, amendments to Instruction 18 based on recent rule changes made by the CFTC with respect to Form CPO–PQR.[443] While the CFTC no longer considers Form PF reporting on commodity pools as constituting substituted compliance with CFTC reporting requirements, some CPOs may continue to report such information on Form PF. Although some commenters recommended that the Commissions harmonize filing requirements between Form PF and Form CPO–PQR,[444] we did not receive comments on the proposed change to the instructions on substituted compliance.

We are adopting, as proposed, amendments to the defined term ''G10,'' which Form PF defines as the Group of Ten, to (1) remove outdated country compositions and (2) include an instruction that if the composition of the G10 changes after the effective date of these amendments to Form PF, advisers should use the current composition as of the data reporting date. In a modification from the proposal, we are not adopting the proposed amendments to the defined term ''EEA,'' as this term is no longer used in the Form following the amendments we are adopting to current Question 28.[445] We are also removing ''EEA'' as a defined term in the Glossary for the same reason. We did not receive comments on these proposed definitional changes.

Additionally, the SEC is making a technical amendment to Section 5 Item B ''Extraordinary Investment Losses'' to correct a mathematical error in the version of the form adopted as part of the May 2023 SEC Form PF Amending Release. [446] Specifically, the SEC is revising the equation in the first sentence so that it accurately reflects that the 10-business-day holding period return computation should be a percentage, rather than a value. To accomplish this, the SEC is deleting the phrase ''of reporting fund aggregate calculated value'' in Section 5 Item B ''Extraordinary Investment Losses'' current report for large hedge fund advisers to qualifying hedge funds.[447]

F. Effective and Compliance Dates

In order to provide time for advisers to prepare to comply with the amendments, including reviewing the requirements, building the appropriate internal reporting and tracking systems, and collecting the required information, as well as to simplify the compliance process and reduce potential confusion, the effective date for the amendments is

[441] We are also adopting amendments to update the mailing address to which advisers requesting a temporary hardship exemption should mail their exemption filing, include the email address for submitting electronically the adviser's signed exemption filing in PDF format, and add an instruction noting that filers should not complete or file any other sections of Form PF if they are filing a temporary hardship exemption. *See* Instruction 14. The reference regarding the instruction pertaining to temporary hardship exemptions has also been amended to refer to Instruction 14 instead of Instruction 13 and, as a result of the amendments set forth in the May 2023 SEC Form PF Amending Release, to refer to section 7 instead of section 5. *See* Form PF General Instruction 3, Section 7—Advisers requesting a temporary hardship exemption.

[442] We are also adopting amendments to 17 CFR 275.204(b)–1(f) under the Advisers Act to remove certain filing instructions in the rule for temporary hardship exemptions and instead direct filers to the instructions in the form. *See* 17 CFR 275.204(b)–1(f)(2)(i) (indicating that advisers should complete and file Form PF in accordance with the instructions to Form PF, no later than one business day after the electronic Form PF filing was due).

[443] *See* Form CPO–PQR Release, *supra* footnote 100.

[444] *See, e.g.,* MFA Comment Letter II; SIFMA Comment Letter.

[445] *See* section II.C.2.d in this Release for further discussion of the amendments to current Question 28.

[446] In May 2023, the SEC amended Form PF section 4, added new sections 5 and 6, and redesignated prior section 5 as section 7 in connection with certain amendments to require event reporting for large hedge fund advisers and all private equity fund advisers and to revise certain reporting requirements for large private equity fund advisers. *See* May 2023 SEC Form PF Amending Release.

[447] As revised, Section 5 Item B states: If on any business day the 10-business-day holding period return of the reporting fund is less than or equal to −20%, provide the information required by Questions 5–4 to 5–7, below. (Current reports should not be filed for overlapping 10-business-day periods.).

the same as the compliance date.[448] The effective/compliance date is March 12, 2025, which is one year from the date of publication of the rules in the **Federal Register**. We recognize that the different effective/compliance date for these amendments from those adopted in the May 2023 SEC Form PF Amending Release and the July 2023 SEC Form PF Amending Release may lead to inconsistent reporting as well as additional compliance burdens because we are amending certain existing questions in Form PF.[449] If a period exists during which some advisers may be completing the old version of these questions and other advisers are completing the amended versions, they may be providing different types of information. This information could be difficult to compare and thus would limit its value for the FSOC and our assessment of systemic risk. However, the amendments we are adopting relate to different sections of Form PF than those adopted in the May 2023 SEC Form PF Amending Release and the July 2023 SEC Form PF Amending Release. Therefore, we will continue to be able to review the data that is reported in sections 1 and 2 of Form PF during the period between the effective/compliance date of the amendments adopted in the May 2023 SEC Form PF Amending Release and the July 2023 SEC Form PF Amending Release. For example, during the transition period between the effective/compliance date of the amendments adopted in May and July, the data reported on sections 1 and 2 of Form PF will retain its comparability as all filers will report on the same sets of questions in these sections.

Some commenters recommended adopting the same effective and compliance date for the amendments proposed in the 2022 SEC Form PF Proposing Release and the 2022 Joint Form PF Proposing Release because it would be more efficient for advisers to implement a single set of changes to its systems.[450] One commenter recommended that the Commissions provide sufficient time for advisers to comply with any new rules arising out of the 2022 SEC Form PF Proposing Release and the 2022 Joint Form PF Proposing Release.[451] One commenter recommended that the Commissions adopt concurrent and overlapping compliance and transition periods for each set of proposed amendments to lessen the burden and expense of compliance.[452]

We recognize that a single set of effective/compliance dates for each set of amendments could potentially provide certain efficiencies for advisers in modifying their existing systems. We considered earlier effective/compliance dates for the amendments adopted in this Release that would align with the effective/compliance dates adopted for the May/July amendments; however, we do not believe that either of the compliance/effective dates for the other amendments to Form PF would provide advisers with sufficient time to comply with the distinct set of amendments that are being adopted in this Release. The compliance/effective dates for the distinct set of Form PF amendments that we are adopting, which apply to different sections of the Form than the May/July amendments to Form PF, are later than the effective/compliance dates of the May/July amendments to allow advisers sufficient time to comply with the amendments that are being adopted in this Release, as well as the May/July amendments.

One commenter recommended a transition period for the change from fiscal quarter to calendar quarter reporting for large hedge fund advisers and large liquidity fund advisers, as discussed more fully in section II.A.3 above.[453] The commenter stated that for quarterly filers who have a fiscal year ending in a non-calendar quarter month, the proposed instructions do not specify the procedure for a filer who, during the transition from fiscal to calendar quarter reporting, would otherwise be required to report twice in one calendar quarter.[454] The commenter recommended that such filers be required to file their first calendar quarter-end filing for the first full quarterly reporting period after the compliance date, to avoid requiring two filings in a single calendar quarter period.[455] After considering comments, we confirm that such an adviser is not required to file its quarterly report more than once in a single calendar quarter as a result of this amendment because advisers are not required to transition to the new timing requirement until the first calendar quarter-end filing for the first full quarterly reporting period after the compliance date.

III. Other Matters

Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs has designated these rules as not a ''major rule'' as defined by 5 U.S.C. 804(2). If any of the provisions of these rules, or the application thereof to any person or circumstance, is held to be invalid, such invalidity shall not affect other provisions or application of such provisions to other persons or circumstances that can be given effect without the invalid provision or application.

IV. Economic Analysis

A. Introduction

The SEC is mindful of the economic effects, including the costs and benefits, of the final amendments. Section 202(c) of the Advisers Act provides that when the SEC is engaging in rulemaking under the Advisers Act and is required to consider or determine whether an action is necessary or appropriate in the public interest, the SEC shall also consider whether the action will promote efficiency, competition, and capital formation, in addition to the protection of investors.[456] The analysis below addresses the likely economic effects of the final amendments, including the anticipated and estimated benefits and costs of the amendments and their likely effects on efficiency, competition, and capital formation. The SEC also discusses the potential economic effects of certain alternatives to the approaches taken in this Release.

As discussed in the proposing release, many of the benefits and costs discussed below are difficult to quantify. For example, in some cases, data needed to quantify these economic effects are not currently available and the SEC does not have information or data that would allow such quantification. While the SEC has attempted to quantify economic

[448] With respect to the compliance period, several commenters requested the SEC consider interactions between the proposed rule and other recent SEC rules. In determining compliance periods, the SEC considers the benefits of the rules as well as the costs of delayed compliance periods and potential overlapping compliance periods. For the reasons discussed throughout this release, to the extent that there are costs from overlapping compliance periods, the benefits of the rule justify such costs. *See* sections IV.B.1 and IV.C.2 of this Release for a discussion of the interactions of the final rule with certain other Commission rules.

[449] For the amendments adopted in the May 2023 SEC Form PF Amending Release, the effective/compliance date for sections 5 and 6 is Dec. 11, 2023, and the effective compliance/date for the amended, existing sections, is June 11, 2024. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4. For the amendments adopted in the July 2023 SEC Form PF Amending Release, the effective/compliance date for the amendments to Form PF is also June 11, 2024. *See* July 2023 SEC Form PF Amending Release, *supra* footnote 4.

[450] *See, e.g.,* MFA Comment Letter III; SIFMA Comment Letter. Subsequent to these comment letters, the SEC adopted amendments to section 3 of Form PF concerning liquidity funds. *See* July 2023 SEC Form PF Amending Release, *supra* footnote 4.

[451] SIFMA Comment Letter.

[452] AIMA/ACC Comment Letter.

[453] *Id.*

[454] *Id.*

[455] *Id.*

[456] 15 U.S.C. 80b–2(c).

effects where possible, much of the discussion of economic effects is qualitative in nature.

B. Economic Baseline and Affected Parties

1. Economic Baseline

The baseline against which the costs, benefits, and the effects on efficiency, competition, and capital formation of the final amendments are measured consists of the current state of the market, Form PF filers' current practices, and the current regulatory framework. The economic analysis appropriately considers existing regulatory requirements, including recently adopted rules, as part of its economic baseline against which the costs and benefits of the final rule are measured.[457]

Several commenters requested the Commission consider interactions between the economic effects of the proposed rule and other recent Commission proposals.[458] Commenters indicated there could be interactions between this rulemaking and six proposals[459] that have since been adopted: the May 2023 SEC Form PF Amending Release,[460] SEC Private Funds Advisers Adopting Release,[461] Beneficial Ownership Amending Release,[462] Short Position Reporting Adopting Release,[463] Securitizations Conflicts Adopting Release,[464] Treasury Clearing Amending Release,[465] and Dealer Definition Amending Release.[466] These recently adopted rules were not included as part of the baseline in the 2022 Joint Form PF Proposing Release because they were not adopted at that time. In response to commenters, this economic analysis considers potential economic effects arising from the extent to which there is any overlap between

[457] *See, e.g., Nasdaq* v. *SEC,* 34 F.4th 1105, 1111–15 (D.C. Cir. 2022). This approach also follows SEC staff guidance on economic analysis for rulemaking. *See* SEC Staff, *Current Guidance on Economic Analysis in SEC Rulemaking* (Mar. 16, 2012), *available at https://www.sec.gov/divisions/riskfin/rsfi_guidance_econ_analy_secrulemaking.pdf* (''The economic consequences of proposed rules (potential costs and benefits including effects on efficiency, competition, and capital formation) should be measured against a baseline, which is the best assessment of how the world would look in the absence of the proposed action.''); *Id.* at 7 (''The baseline includes both the economic attributes of the relevant market and the existing regulatory structure.''). The best assessment of how the world would look in the absence of the proposed or final action typically does not include recently proposed actions, because doing so would improperly assume the adoption of those proposed actions.

[458] *See, e.g.,* MFA Comment Letter III; SIFMA Comment Letter; AIC Comment Letter I; AIC Comment Letter II; MFA/NAPFM Comment Letter; Comment Letter of U.S. House of Representatives Committee on Financial Services.

[459] Amendments to Form PF to Require Current Reporting and Amend Reporting Requirements for Large Private Equity Advisers and Large Liquidity Fund Advisers, Release No. IA–5950 (Jan. 26, 2022) [87 FR 9106 (Feb. 17, 2022)] (*see* MFA/NAPFM Comment Letter at 20, n.21 and accompanying text; AIC Comment Letter II at 8, n.25); Private Fund Advisers; Documentation of Registered Investment Adviser Compliance Reviews, Release No. IA–5955 (Feb. 9, 2022) [87 FR 16886 (Mar. 24, 2022)] (*see* MFA/NAPFM Comment Letter at 10–12; AIC Comment Letter II at 1, n.3, 8); Modernization of Beneficial Ownership Reporting, Release Nos. 33–11030, 34–94211 (Feb. 10, 2022) [87 FR 13846 (Mar. 10, 2022)] (*see* MFA/NAPFM Comment Letter at 14–15); Short Position and Short Activity Reporting by Institutional Investment Managers, Release No. 34–94313 (Feb. 25, 2022) [87 FR 14950 (Mar. 16, 2022)] (*see* MFA/NAPFM Comment Letter at 15–16); Prohibition Against Conflicts of Interest in Certain Securitizations, Release No. 33–11151 (Jan. 25, 2023) [88 FR 9678 (Feb. 14, 2023)] (*see* MFA/NAPFM Comment Letter at 21–22); Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule With Respect to U.S. Treasury Securities, Release No. 34–95763 (Sept. 14, 2022) [87 FR 64610 (Oct. 25, 2022)] (*see* July 2023 MFA and NAPFM Comment Letter at 16–17); Further Definition of ''As a Part of a Regular Business'' in the Definition of Dealer and Government Securities Dealer, Release No. 34–94524 (Mar. 28, 2022) [87 FR 23054 (Apr. 18, 2022)] (*see* MFA/NAPFM Comment Letter at 12–13; AIC Comment Letter II at n.3, n.16, n.30).

[460] May 2023 SEC Form PF Amending Release, *supra* footnote 4. The Form PF amendments adopted in May 2023 require large hedge fund advisers and all private equity fund advisers to file reports upon the occurrence of certain reporting events. The May 2023 SEC Form PF Amending Release revised Form PF to (i) add new current reporting requirements for large hedge fund advisers to qualifying hedge funds upon the occurrence of key events (new section 5); (ii) add new quarterly reporting requirements for all private equity fund advisers upon the occurrence of key events (new section 6); and (iii) add and revise new regular reporting questions for large private equity fund advisers. The compliance dates are Dec. 11, 2023, for the event reports in Form PF sections 5 and 6, and June 11, 2024, for the remainder of the Form PF amendments in the May 2023 SEC Form PF Amending Release.

[461] SEC Private Fund Advisers Adopting Release, *supra* footnote 185. The Commission adopted five new rules and two rule amendments as part of the reforms. The compliance date for the quarterly statement rule and the audit rule is Mar. 14, 2025, for all advisers. For the adviser-led secondaries rule, the preferential treatment rule, and the restricted activities rule, the Commission adopted staggered compliance dates that provide for the following transition periods: for advisers with $1.5 billion or more in private funds assets under management, a 12-month transition period (ending on Sept. 14, 2024) and for advisers with less than $1.5 billion in private funds assets, an 18-month transition period (ending on Mar. 14, 2025). The compliance date for the amended Advisers Act compliance rule was Nov. 13, 2023.

[462] Modernization of Beneficial Ownership Reporting, Release No. 33–11253 (Oct. 10, 2023) (''Beneficial Ownership Amending Release''). Among other things, the amendments generally shorten the filing deadlines for initial and amended beneficial ownership reports filed on Schedules 13D and 13G, and require that Schedule 13D and 13G filings be made using a structured, machine-readable data language. The amendments are effective on Feb. 5, 2024. Compliance with the new filing deadline for Schedule 13G will not be required before Sept. 30, 2024, and the rule's structured data requirements have a one-year implementation period ending Dec. 18, 2024. *See* Beneficial Ownership Amending Release, section II.G.

[463] Short Position and Short Activity Reporting by Institutional Investment Managers, Release No. 34–98738 (Oct. 13, 2023) [88 FR 75100 (Nov. 1, 2023)] (''Short Position Reporting Adopting Release''). The new rule and related form are designed to provide greater transparency through the publication of short sale-related data to investors and other market participants. Under the new rule, institutional investment managers that meet or exceed certain specified reporting thresholds are required to report, on a monthly basis using the related form, specified short position data and short activity data for equity securities. The compliance date for the rule is Jan. 2, 2025. In addition, the Short Position Reporting Adopting Release amends the national market system plan governing consolidated audit trail (''CAT'') to require the reporting of reliance on the bona fide market making exception in the Commission's short sale rules. The compliance date for the CAT amendments is July 2, 2025.

[464] Prohibition Against Conflicts of Interest in Certain Securitizations, Release No. 33–11254 (Nov. 27, 2023) [88 FR 85396 (Dec. 7, 2023)] (''Securitizations Conflicts Adopting Release''). The new rule prohibits an underwriter, placement agent, initial purchaser, or sponsor of an asset-backed security (including a synthetic asset-backed security), or certain affiliates or subsidiaries of any such entity, from engaging in any transaction that would involve or result in certain material conflicts of interest. The compliance date is June 9, 2025.

[465] Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule with Respect to U.S. Treasury Securities, Release No. 34–99149 (Dec. 13, 2023) [89 FR 2714 (Jan. 16, 2024)] (''Treasury Clearing Adopting Release''). Among other things, the rules require covered clearing agencies for U.S. Treasury securities to have written policies and procedures reasonably designed to require that every direct participant of the covered clearing agency submit for clearance and settlement all eligible secondary market transactions in U.S. Treasury securities to which it is a counterparty. The compliance dates are 60 days after publication in the **Federal Register** for each covered clearing agency to file any proposed rule changes pursuant to final Rule 17Ad–22(e)(6)(i), 17Ad–22(e)(18)(iv)(c), and 15c3–3, and the rule changes must be effective by Mar. 31, 2025. With respect to the changes to Rule 17Ad–22(e)(18)(iv)(A) and (B), (i) each covered clearing agency will be required to file any proposed rule changes regarding those amendments no later than 150 days after publication in the **Federal Register**, and the proposed rule changes must be effective by Dec. 31, 2025, for cash market transactions encompassed by section (ii) of the definition of an eligible secondary market transaction, and by June 30, 2026, for repo transactions encompassed by section (i) of the definition of an eligible secondary market transactions. Compliance by the direct participants of a U.S. Treasury securities covered clearing agency with the requirement to clear eligible secondary market transactions would not be required until Dec. 31, 2025 and June 30, 2026, respectively, for cash and repo transactions.

[466] Further Definition of ''As a Part of a Regular Business'' in the Definition of Dealer and Government Securities Dealer in Connection with Certain Liquidity Providers, Release No. 34–99477 (Jan. 24, 2024) (''Dealer Definition Amending Release''). The dealer definition amendments define the phrase ''as a part of a regular business'' as used in the statutory definitions of ''dealer'' and ''government securities dealer.'' The compliance date is one year from the effective date, or approximately Mar. 2025, for persons engaging in activities that meet the dealer registration requirements to register prior to the effective date of the final rules.

the compliance period for the final amendments and the compliance periods for each of these recently adopted rules.[467]

Form PF complements the basic information about private fund advisers and funds reported on Form ADV.[468] As discussed above, the Commissions adopted Form PF in 2011, with additional amendments made to section 3 along with certain money market reforms in 2014,[469] further amendments made to sections 3 and 4 in 2023, and new sections 5 and 6 added in 2023 as well.[470] Unlike Form ADV, Form PF is not an investor-facing disclosure form. Information that private fund advisers report on Form PF is provided to regulators on a confidential basis and is nonpublic.[471] The purpose of Form PF is to provide the Commissions and FSOC with data that regulators can deploy in their regulatory and oversight programs directed at assessing and managing systemic risk and protecting investors.[472]

Before Form PF was adopted, the SEC and other regulators, including the CFTC, had limited visibility into the economic activity of private fund advisers and relied largely on private vendor databases about private funds that covered only voluntarily provided private fund data and did not represent the total population.[473] Form PF represented an improvement in available data about private funds, both in terms of its reliability and completeness.[474] Generally, investment advisers registered (or required to be registered) with the SEC with at least $150 million in private fund assets under management must file Form PF. Smaller private fund advisers and all private equity fund advisers file annually to report general information such as the types of private funds advised (*e.g.,* hedge funds, private equity funds, or liquidity funds), fund size, use of borrowings and derivatives, strategy, and types of investors.[475] In addition, large private equity fund advisers provide data about each private equity fund they manage. Large hedge fund advisers and large liquidity fund advisers also provide data about each reporting fund they manage, and are required to file quarterly, currently after each fiscal quarter.[476]

The SEC and other regulators now have almost a decade of experience with analyzing the data collected on Form PF. The collected data has helped FSOC establish a baseline picture of the private fund industry for the use in assessing systemic risk[477] and improved the SEC's oversight of private fund advisers.[478] Form PF data also has enhanced the SEC's and FSOC's ability to frame regulatory policies regarding the private fund industry, its advisers, and the markets in which they participate, as well as more effectively evaluate the outcomes of regulatory policies and programs directed at this sector, including the management of systemic risk and the protection of investors.[479] Additionally, based on the data collected through Form PF filings, regulators have been able to regularly inform the public about ongoing private fund industry statistics and trends by generating quarterly Private Fund Statistics reports[480] and by making publicly available certain results of staff research regarding the characteristics, activities, and risks of private funds.[481] As discussed above, these data may also be used by the CFTC for the purposes of its regulatory programs, including examinations, investigations and investor protection efforts.[482]

However, this decade of experience with analyzing Form PF data has also highlighted certain limitations of information collected on Form PF, including information gaps and situations where more granular and timely information would improve the SEC's and FSOC's understanding of the private fund industry and the potential systemic risk relating to its activities, and improve regulators' ability to protect investors.[483] For example, as discussed above, when monitoring funds' activities during recent market events like the March 2020 COVID–19 turmoil, the existing aggregation of U.S. Treasury securities with related derivatives did not reflect the role hedge funds played in the U.S. Treasury

[467] In addition, commenters indicated there could also be overlapping compliance costs between the final amendments and proposals that have not been adopted. *See, e.g.,* AIC Comment Letter II; MFA/NAPFM Comment Letter. To the extent those proposals are adopted, the baseline in those subsequent rulemakings will reflect the existing regulatory requirements at that time.

[468] Investment advisers to private funds report on Form ADV, on a public basis, general information about private funds that they advise, including basic organizational, operational information, and information about the fund's key service providers. Information on Form ADV is available to the public through the Investment Adviser Public Disclosure System, which allows the public to access the most recent Form ADV filing made by an investment adviser. *See, e.g.,* Form ADV, *available at https://www.investor.gov/introduction-investing/investing-basics/glossary/form-adv; see also* Investment Adviser Public Disclosure, *available at https://adviserinfo.sec.gov/.*

[469] *See supra* footnote 3. When the SEC adopted the amendments to section 3 in 2014 in connection with certain money market reforms, it noted that under the proposal it was concerned that some of the proposed money market reforms might result in assets shifting from registered money market funds to unregistered products such as liquidity funds, and that the proposed amendments were designed to help the SEC and FSOC track any potential shift in assets and better understand the risks associated with the proposed money market reforms. *See, e.g.,* D. Hiltgen, Private Liquidity Funds: Characteristics and Risk Indicators (Jan. 27, 2017), *available at https://www.sec.gov/files/2017-03/Liquidity%20Fund%20Study.pdf* (''Hiltgen Paper''); 2011 Form PF Adopting Release, *supra* footnote 4; 2014 Form PF Amending Release, *supra* footnote 4, at 466; Commissioner Luis Aguilar Statement, *Strengthening Money Market Funds to Reduce Systemic Risk,* SEC (July 23, 2014), *available at https://www.sec.gov/news/public-statement/2014-07-23-open-meeting-statment-laa.*

[470] May 2023 SEC Form PF Amending Release, *supra* footnote 4; July 2023 SEC Form PF Amending Release *supra* footnote 4.

[471] As discussed above, SEC staff publish quarterly reports of aggregated and anonymized data regarding private funds on the SEC's website. *See supra* footnote 5; *see also* Private Fund Statistics Q1 2023.

[472] *See supra* section I.

[473] *See, e.g.,* SEC 2020 Annual Staff Report Relating to the Use of Form PF Data (Nov. 2020), *available at https://www.sec.gov/files/2020-pf-report-to-congress.pdf.*

[474] *Id.*

[475] *Id.*

[476] *Id.; see also supra* section II.A.3.

[477] *See, e.g.,* OFR, 2021 Annual Report to Congress (Nov. 2021), *available at https://www.financialresearch.gov/annual-reports/files/OFR-Annual-Report-2021.pdf;* Financial Stability Oversight Council, 2020 Annual Report, *available at https://home.treasury.gov/system/files/261/FSOC2020AnnualReport.pdf.*

[478] *See, e.g.,* SEC 2020 Staff Report, *supra* footnote 473.

[479] *See supra* footnotes 477, 478.

[480] *See supra* footnote 471.

[481] *See, e.g.,* David C. Johnson & Francis A. Martinez, *Form PF Insights on Private Equity Funds and Their Portfolio Companies,* OFR Brief Series No. 18–01 (June 14, 2018), *available at https://www.financialresearch.gov/briefs/2018/06/14/form-pf-insights-on-private-equity-funds/;* Hiltgen Paper, *supra* footnote 470; George Aragon, A. Tolga Ergun, Mila Getmansky & Giulio Girardi, *Hedge Funds: Portfolio, Investor, and Financing Liquidity* (May 17, 2017), *available at https://www.sec.gov/files/dera_hf-liquidity.pdf;* George Aragon, Tolga Ergun & Giulio Girardi, *Hedge Fund Liquidity Management: Insights for Fund Performance and Systemic Risk Oversight* (May 2017), *available at https://www.sec.gov/files/dera_hf-liquidity-management.pdf;* Mathis S. Kruttli, Phillip J. Monin & Sumudu W. Watugala, *The Life of the Counterparty: Shock Propagation in Hedge Fund-Prime Broker Credit Networks* (OFR Working Paper No. 19–03, Oct. 2019), *available at https://www.financialresearch.gov/working-papers/files/OFRwp-19-03_the-life-of-the-counterparty.pdf;* Mathias S. Kruttli, Phillip J. Monin, Lubomir Petrasek & Sumudu W. Watugala, *Hedge Fund Treasury Trading and Funding Fragility: Evidence from the COVID–19 Crisis,* Fed. Rsrv. Bd., Fin. and Econ. Discussion Series No. 2021–038 (Apr. 2021), *available at https://www.federalreserve.gov/econres/feds/hedge-fund-treasury-trading-and-funding-fragility-evidence-from-the-covid-19-crisis.htm;* Mathias S. Kruttli, Phillip J. Monin & Sumudu W. Watugala, *Investor Concentration, Flows, and Cash Holdings: Evidence from Hedge Funds,* Fed. Rsrv. Bd., Fin. and Econ. Discussion Series No. 2017–121 (Dec. 15, 2017), *available at https://www.federalreserve.gov/econres/feds/investor-concentration-flows-and-cash-holdings-evidence-from-hedge-funds.htm.*

[482] *See supra* section I.

[483] *See supra* section I.

market.[484] Also during the COVID–19 market turmoil, FSOC sought to evaluate the role hedge funds played in disruptions in the U.S. Treasury market by unwinding cash-futures basis trade positions and taking advantage of the near-arbitrage between cash and futures prices of U.S. Treasury securities. Because the existing requirement regarding turnover reporting on U.S. Treasury securities is highly aggregated, the SEC staff, during retrospective analyses on the March 2020 market events, was unable to obtain a complete picture of activity relating to long treasuries and treasury futures.[485] The need for more granular information collected on Form PF is further heightened by the increasing significance of the private fund industry to financial markets, and resulting regulatory concerns regarding potential risks to U.S. financial stability from this sector.[486] The SEC's and FSOC's experiences analyzing Form PF data has also identified certain areas of Form PF where questions result in data received that is redundant to other questions, or instructions that result in unnecessary reporting burden for some advisers.[487]

2. Affected Parties

The final rule amends the general instructions and basic information reporting requirements facing all categories of private fund advisers. As discussed above, these include, but are not limited to, advisers to hedge funds, private equity funds, real estate funds, securitized asset funds, liquidity funds, and venture capital funds.[488] The final rule further amends reporting requirements for large hedge fund advisers, including specific revisions for large hedge fund advisers to qualifying hedge funds.[489]

Hedge funds, the focus of part of the release, are one of the largest categories of private funds,[490] and as such play an important role in the U.S. financial system due to their ability to mobilize large pools of capital, take economically important positions in a market, and their extensive use of leverage, derivatives, complex structured products, and short selling.[491] While these features may enable hedge funds to generate higher returns as compared to other investment alternatives, the same features may also create spillover effects in the event of losses (whether caused by their investment and derivatives positions or use of leverage or both) that might lead to significant stress or failure not just at the affected fund but also across financial markets.[492]

In the first quarter of 2023, there were 9,846 hedge funds reported on Form PF, managed by 1,856 advisers, with almost $9.5 trillion in gross assets under management, which represented almost half of gross assets reported by private fund advisers.[493] Currently, hedge fund advisers with between $150 million and $2 billion in regulatory assets (that do not qualify as large hedge fund advisers) file Form PF annually, in which they provide general information about funds they advise such as the types of private funds advised, fund size, their use of borrowings and derivatives, strategy, and types of investors. Large hedge fund advisers (those with at least $1.5 billion in regulatory assets under management attributable to hedge funds) [494] file Form PF quarterly, in which they provide data about each hedge fund they managed during the reporting period (irrespective of the size of the fund).[495] Large hedge fund advisers must report more information on Form PF about qualifying hedge funds (those with at least $500 million as of the last day of any month in the fiscal quarter immediately preceding the adviser's most recently completed fiscal quarter) [496] than other hedge funds they manage during the reporting period. In the first quarter of 2023, there were 2,034 qualifying hedge funds reported on Form PF, managed by 570 advisers, with almost $8 trillion in gross assets under management, which represented almost 84 percent of the reported hedge fund assets.[497]

Private equity funds are another large category of funds in the private fund industry. In the first quarter of 2023, there were 20,917 private equity funds reported on Form PF, managed by 1,755 advisers, with $6.6 trillion in gross assets under management, which represented almost one third of the reported gross assets in the private fund industry.[498] Many private equity funds focus on long-term returns by investing in a private, non-publicly traded

[484] *See supra* section II.C.2.a.

[485] *See supra* section II.C.2.d. This also includes the SEC's and FSOC's experience analyzing data from multiple regulatory filings. For example, one SEC staff paper has used Form PF data and Form N–MPF data to study rule 2a–7 risk limits and implications of money market reforms. *See, e.g.,* Hiltgen Paper, *supra* footnote 470.

[486] The private fund industry has experienced significant growth in size and changes in terms of business practices, complexity of fund structures, and investment strategies and exposures in the past decade. *See supra* footnote 5; *see also Financial Stability Oversight Council Update on Review of Asset Management Product and Activities* (2014), *available at https://home.treasury.gov/system/files/261/Financial%20Stability%20Oversight%20Council%20Update%20on%20Review%20of%20Asset%20Management%20Products%20and%20Activities.pdf.*

[487] Based on the analysis in section V.C., the current costs associated with filing Form PF report are estimated to be $4,815 annually for smaller private fund advisers, $48,150 per quarterly filing or $192,600 annually for large hedge fund advisers, $22,470 per quarterly filing or $89,880 annually for large liquidity fund advisers, and $41,730 annually for large private equity fund advisers. A 2018 industry survey of large hedge fund advisers observed filing costs that ranged from 35% to 72% higher than SEC cost estimates. *See* MFA Letter to Chairman Clayton, *supra* footnote 164. However, a 2015 academic survey of SEC-registered investment advisers to private funds affirmed the SEC's cost estimates for smaller private fund advisers' Form PF compliance costs, and observed that the SEC overestimated Form PF compliance costs for larger private fund advisers. *See* Wulf Kaal, *Private Fund Disclosures Under the Dodd-Frank Act,* 9 Brooklyn J. Corp., Fin., and Com. L. 428 (2015).

[488] *See supra* section I.

[489] Form PF currently defines ''hedge fund'' broadly to include any private fund (other than a securitized asset fund) that has any of the following three characteristics: (1) a performance fee or allocation that takes into account unrealized gains, or (2) a high leverage (*i.e.,* the ability to borrow more than half of its net asset value (including committed capital) or have gross notional exposure in excess of twice its net asset value (including committed capital)), or (3) the ability to short sell securities or enter into similar transactions (other than for the purpose of hedging currency exposure or managing duration). Any non-exempt commodity pools about which an investment adviser is reporting or required to report are automatically categorized as hedge funds. Excluded from the ''hedge fund'' definition in Form PF are vehicles established for the purpose of issuing asset backed securities (''securitized asset funds''). *See* Form PF Glossary of Terms. ''Large'' hedge fund advisers are those, collectively with their related persons, with at least $1.5 billion in hedge fund assets under management as of the last day of any month in the fiscal quarter immediately preceding the adviser's most recently completed fiscal quarter. Qualifying hedge funds are hedge funds that have a net asset value (individually or in combination with any feeder funds, parallel funds and/or dependent parallel managed accounts) of at least $500 million as of the last day of any month in the fiscal quarter immediately preceding the adviser's most recently completed fiscal quarter. *See supra* section II.C.

[490] *See infra* footnote 493.

[491] *See, e.g.,* Lloyd Dixon, Noreen Clancy & Krishna B. Kumar, *Hedge Fund and Systemic Risk,* RAND Corp. (2012); John Kambhu, Til Schuermann & Kevin Stiroh, *Hedge Funds, Financial Intermediation, and Systemic Risk,* Fed. Rsrv. Bank of NY's Econ. Policy Rev. (2007).

[492] *See supra* footnotes 477, 486.

[493] In the first quarter of 2023, hedge fund assets accounted for approximately 46.3% of the gross asset value (''GAV'') ($9.5/$20.5 trillion) and approximately 34.8% of the net asset value (''NAV'') ($4.9/14.0 trillion) of all private funds reported on Form PF. Private Fund Statistics Q1 2023, at 5.

[494] *See supra* footnote 489.

[495] Currently, Instruction 9 requires large hedge fund advisers to update Form PF within 60 days after the end of each fiscal quarter. *See supra* section II.A.3.

[496] *Id.*

[497] In the first quarter of 2023, qualifying hedge fund assets accounted for 84% of the GAV ($8.0/$9.5 trillion) and 79% of the NAV ($3.9/$4.9 trillion) of all hedge funds reported on Form PF. Private Fund Statistics Q1 2023, at 4–5.

[498] In the first quarter of 2023, private equity assets accounted for 32.4% of the GAV ($6.6/$20.5 trillion) and 42.7% of the NAV ($6.0/$14.0 trillion) of all private funds reported on Form PF. Private Fund Statistics Q1 2023, at 5.

company or business—the portfolio company—and engage actively in the management and direction of that company or business in order to increase its value.[499] Other private equity funds may specialize in making minority investments in fast-growing companies or startups.[500]

For the remaining categories of funds (real estate funds, securitized asset funds, liquidity funds, venture capital funds, and other private funds), advisers required to file Form PF had, in the first quarter of 2023, investment discretion over almost $4.4 trillion in gross assets under management.[501] These assets were managed by 1,709 fund advisers managing 16,668 funds.[502]

Private funds are typically limited to accredited investors and qualified clients such as pension funds, insurance companies, foundations and endowments, and high income and net worth individuals.[503] Private funds that rely on the exclusion from the definition of ''investment company'' provided in section 3(c)(7) of the Investment Company Act are limited to investors that are also qualified purchasers (as defined in section 2(a)(51) of the Investment Company Act). Retail U.S. investors with exposure to private funds are typically invested in private funds indirectly through public and private pension plans and other institutional investors.[504] In the first quarter of 2023, public pension plans had $1,905 billion invested in reporting private funds while private pension plans had $1,302 billion invested in reporting private funds, making up 13.6 percent and 9.3 percent of the overall beneficial ownership in the private fund industry, respectively.[505] Private fund advisers have also sought to be included in individual investors' retirement plans, including their 401(k)s.[506]

[499] After purchasing controlling interests in portfolio companies, private equity fund advisers frequently get involved in managing those companies by serving on the company's board; selecting and monitoring the management team; acting as sounding boards for CEOs; and sometimes stepping into management roles themselves. *See, e.g.,* SEC, *Private Equity Funds, Investor.gov, available at https://www.investor.gov/introduction-investing/investing-basics/investment-products/private-investment-funds/private-equity.*

[500] *Id.*

[501] Private Fund Statistics Q1 2023, at 5.

[502] Private Fund Statistics Q1 2023, at 4.

[503] *See, e.g.,* Private Equity Funds, *supra* footnote 499; SEC, *Hedge Funds, Investor.gov, available at https://www.investor.gov/introduction-investing/investing-basics/investment-products/private-investment-funds/hedge-funds.*

[504] *See supra* footnote 503.

[505] Private Fund Statistics Q1 2023, at 15.

[506] *See, e.g.,* Dep't of Labor, Information Letter (June 3, 2020), *available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/information-letters/06-03-2020.*

C. Benefits, Costs, and Effects on Efficiency, Competition, and Capital Formation

1. Benefits

The final amendments are designed to facilitate two primary goals the SEC sought to achieve with reporting on Form PF as articulated in the original adopting release, namely: (1) facilitating FSOC's understanding and monitoring of potential systemic risk relating to activities in the private fund industry and assisting FSOC in determining whether and how to deploy its regulatory tools with respect to nonbank financial companies; and (2) enhancing the SEC's abilities to evaluate and develop regulatory policies and improving the efficiency and effectiveness of the SEC's efforts to protect investors and maintain fair, orderly, and efficient markets.[507]

The SEC believes the final amendments will accomplish these goals in three key ways, each discussed in detail in the following sections. First, the final amendments will provide solutions to potential reporting errors and issues of data quality when analyzing Form PF filings across advisers and when analyzing multiple different regulatory filings. Higher quality data across different funds and across different regulatory filings can allow the SEC and FSOC to develop an understanding of one set of advisers and apply it to other advisers more rapidly, or apply lessons from one financial market to other financial markets. This can help the SEC and FSOC develop more effective regulatory responses and oversight, and help the SEC protect investors by identifying areas in need of outreach, examinations, and investigations in response to potential systemic risks, conflicting arrangements between advisers and investors, and other sources of investor harm.

Second, the final amendments will help Form PF more completely and accurately capture information relevant to ongoing trends in the private fund industry in terms of ownership, size, investment strategies, and exposures. This can improve the SEC's and FSOC's understanding of new developing systemic risks and potential conflicting arrangements, thereby further aiding in the development of regulatory responses, and also aiding the SEC in efforts to protect investors by identifying areas in need of outreach, examinations, and investigations.

Third, the final amendments will take certain steps to streamline certain reporting and reduce certain reporting burdens without compromising investor protection efforts and systemic risk analysis. This will improve the efficiency and effectiveness of the SEC's efforts to protect investors and maintain fair, orderly and efficient markets.

The SEC anticipates that the increased ability for the SEC's and FSOC's oversight, resulting from the final amendments, might promote better functioning and more stable financial markets, which may lead to efficiency improvements. The SEC does not anticipate significant benefits on competition in the private fund industry from the final amendments because the reported information generally will be nonpublic and similar types of advisers will have comparable burdens under the amended Form. For similar reasons, the SEC does not anticipate significant effects of the amendments on capital formation.

Several of these amendments have been revised relative to the proposal. The revisions include changes to instructions for purposes of clarification, revising framing or explanation of questions where commenters made suggestions to improve data quality, revising instructions to avoid duplicative reporting or to otherwise ease burden, or forgoing adopting certain amendments entirely. We include in the discussion in this section how the benefits are impacted by changes made in response to commenters. In general, revisions either (1) enhance the benefits or (2) may reduce the benefits but substantially reduce the costs.[508]

The final amendments revise the general instructions (as well as implement additional amendments), section 1 (requiring basic information about advisers and the private funds they advise), and section 2 (requiring information about hedge funds advised by large private fund advisers) of Form PF. The benefits associated with each of these specific elements are discussed in greater detail below.

a. Amendments to General Instructions, Amendments To Enhance Data Quality, and Additional Amendments

The amendments update the Form PF general instructions to revise how all private fund advisers satisfy certain requirements on Form PF, issue a series of amendments to enhance data quality,

[507] *See supra* section I. While the final amendments are also designed to improve the usefulness of this data for the CFTC, this economic analysis does not include the benefits associated with enhancements to the CFTC's use of reporting on Form PF.

[508] We discuss the impacts on costs below. *See infra* section IV.C.2.

and issue a series of additional amendments.[509] There are five categories of these amendments.

First, the amendments revise the general instructions for reporting of master-feeder arrangements and parallel fund structures.[510] These revisions to the general instructions will improve consistency of reporting associated with measuring private fund interconnectedness and investment in other private funds by revising instructions for reporting of ownership structures and revising instructions that are currently ambiguous and result in reporting errors and issues of data quality across advisers. For example, as discussed above, Form PF currently provides advisers with flexibility to respond to questions regarding master-feeder arrangements, parallel fund structures either in the aggregate or separately, as long as they do so consistently throughout Form PF. The revised instructions will specify how to respond to these questions to prevent some advisers from responding in the aggregate and some advisers from responding separately.[511] The revised instructions will also require reporting on the total value of parallel managed accounts.[512] The SEC anticipates these improved data will assist the SEC and FSOC in assessing potential risks to financial stability resulting from increasingly complex ownership and investment structures of private funds. While master-feeder arrangements, parallel fund structures, and use of funds of funds all allow private funds to benefit from larger pools of capital, diversify risk, and enjoy shared returns,[513] these same features have inherent risks of spillovers in losses, as losses in a master fund or underlying investment of a fund of funds cause losses in connected funds as well. Complex ownership structures may also create conflicts of interest when the same individuals serve as directors on boards of both master and feeder funds under a single owner,[514] and may also mask instances of fraud and a private fund's methods for committing fraud.[515] Investor protection efforts will therefore benefit from more consistent data providing connections from master funds to feeder funds and other ownership information.

While some commenters supported the proposed amendments on this topic,[516] other commenters opposed the proposed amendments as of limited benefit to the Commissions and/or FSOC.[517] For example, as discussed above, disaggregated data of these structures will provide the Commissions and FSOC with increased transparency into risk profiles and complex fund structures, which will improve our ability to monitor systemic risk and protect investors.[518] We also disagree that disaggregated reporting of master-feeder funds and parallel fund structures will be of limited value based on our experience with Form PF, which currently obscures our understanding of their fund structures and the risk exposure of their component funds.[519] We also believe that the disaggregated reporting will allow for a clearer understanding of a fund's structure.[520]

Commenters also stated that disaggregated data would provide misleading information by reporting data in isolation as opposed to as part of an overall fund or investment program.[521] We disagree, and think that disaggregated data will not be misleading to the Commissions or FSOC in comparison to aggregated data because the Commissions and FSOC could, if necessary, aggregate the data to understand the overall fund.[522] Similarly, as another example, data regarding the total value of parallel managed accounts, however, will allow FSOC to take into account the greater amount of assets an adviser may be managing using a given strategy for purposes of analyzing the data reported on Form PF for systemic risk purposes.[523]

Certain changes made in response to commenters' concerns will also enhance these benefits relative to the proposal. For example, by modifying the instructions for how a feeder fund determines its reporting category to specify that the feeder fund should exclude any of its holdings in the master fund's equity when calculating its total asset value for the purpose of determining its reporting category, the amendments will avoid double counting of reported assets, given that data for the master fund will be separately reported on Form PF.[524]

Second, the amendments revise the general instructions for reporting for private funds that invest in other funds or trading vehicles.[525] Specifically, the amendments revise Instruction 7 and 8 to require advisers to include information pertaining to their trading vehicles when completing Form PF.[526]

[509] *See supra* sections II.A, II.D, II.E.

[510] *See supra* section II.A.1. However, an adviser will continue to aggregate these structures for purposes of determining whether the adviser meets a reporting threshold.

[511] Similar benefits will be obtained from revisions to Instruction 7, which requires advisers to include the value of investments in other private funds when determining whether the adviser meets the thresholds for reporting as a large hedge fund adviser, large liquidity fund adviser, or large private equity fund adviser, and whether a private fund is a qualifying hedge fund; and generally requires an adviser to include the value of a reporting fund's investments in other private funds when responding to questions on Form PF. Other revisions could also provide benefits associated with consistency of reporting by revising instructions to avoid error across filers, including amending instructions to provide that advisers must not ''look through'' its investments in other private funds when responding to questions and adding an instruction when ''looking through'' cannot be avoided; providing general instructions to explain how advisers will report information if the reporting fund uses a trading vehicle; and amending instructions to indicate that advisers must not ''look through'' a reporting fund's investments in funds or other entities that are not private funds, or trading vehicles. *See supra* section II.A.2. Similar benefits will also be obtained from the amendments updating instructions to provide conformity with CFTC's amendments to Form CPO–PQR, including those that specify when advisers that are also CPOs should complete particular sections of Form PF. *See supra* section II.E; *see also* Revised Instruction 18.

[512] *See supra* section II.A.1.

[513] *See, e.g.,* Robert Harris, Tim Jenkinson, Steven Kaplan & Ruediger Stucke, *Financial Intermediation in Private Equity: How Well Do Funds of Funds Perform?,* 129 J. Fin. Econ. 2, 287–305 (Aug. 2018).

[514] *See, e.g.,* Todd Ehret, *Platinum Fraud Charges Shine Light On Cayman Director Responsibilities,* Reuters Fin. Reg. Forum (Mar. 30, 2017), *available at https://www.reuters.com/article/bc-finreg-cayman-private-structure/platinum-fraud-charges-shine-light-on-cayman-director-responsibilities-idUSKBN17030J.*

[515] *See, e.g.,* Melvyn Teo, *Lessons Learned from Hedge Fund Fraud,* Eureka Hedge (Oct. 2009), *available at https://www.eurekahedge.com/Research/News/506/Lessons-Learned-From-Hedge-Fund-Fraud.*

[516] *See supra* section II.A.1; *see also* AFREF Comment Letter I; Better Markets Comment Letter.

[517] *See supra* section II.A.1; *see also* AIC Comment Letter I; AIMA/ACC Comment Letter; MFA Comment Letter II.

[518] *See supra* section II.A.1.

[519] *Id.*

[520] *Id.*

[521] *See, e.g.,* MFA Comment Letter II; USCC Comment Letter.

[522] *See supra* section II.A.1.

[523] *Id.*

[524] *Id.*

[525] These final amendments will include requiring advisers to include the value of investments in other private funds in determining whether the adviser is required to file Form PF and when determining whether the adviser meets the thresholds for reporting as a large hedge fund adviser, large liquidity fund adviser, or large private equity fund adviser, and whether a private fund is a qualifying hedge fund; generally requiring an adviser to include the value of a reporting fund's investments in other private funds when responding to questions on Form PF; provide that generally advisers must not ''look through'' its investments in other private funds (other than a trading vehicle) when responding to questions and adding an instruction to provide that advisers must provide an explanation if ''looking through'' cannot be avoided; amending the general instructions to explain how advisers will report information if the reporting fund uses a trading vehicle; requiring advisers to report all trading vehicles, whether wholly owned or partially owned, on a consolidated bases; and amending instructions to indicate that advisers must not ''look through'' a reporting fund's investments in funds or other entities that are not private funds or trading vehicles. *See supra* section II.A.2.

[526] *See supra* section II.A.2.

Because private funds may use trading vehicles for a wide variety of purposes, more complete and accurate visibility into asset class exposures, position sizes, and counterparty exposures relied on by trading vehicles can enhance the SEC's and FSOC's systemic risk and financial stability assessment efforts and the SEC's efforts to protect investors by identifying areas in need of outreach, examination, or investigation.

Certain changes made in response to commenters' concerns will also enhance these benefits relative to the proposal. For example, one commenter stated that allowing an adviser to determine whether to include or exclude a reporting fund's investment in other private funds could result in distortions in the data collected on Form PF.[527] By modifying the instructions to provide specific instructions, such distortion can be avoided, which will improve data quality.[528]

As another example, commenters opposed proposed amendments that would have permitted an adviser to select whether to report a wholly owned trading vehicle on either a consolidated or disaggregated basis and would have required advisers to report a partially owned trading vehicle on a disaggregated basis.[529] These commenters questioned the benefits of these proposed amendments, for example stating that separate reporting for trading vehicles is not necessary because trading vehicles are often used for administrative purposes, such as for tax or efficiency purposes, but are managed on a consolidated basis and regarded as a single entity for investment purposes.[530] By instead requiring advisers to report all trading vehicles, whether wholly owned or partially owned, on a consolidated basis, and by specific questions relating to a reporting fund's trading vehicle use and a trading vehicle's position size and risk exposure, we will improve data comparability and allow us to better understand the holdings and exposures of the fund structure for our assessments of potential systemic risk.

Third, the amendments will revise the general instructions for reporting timelines by revising Instruction 9 to require large hedge fund advisers and large liquidity fund advisers to update Form PF within a certain number of days after the end of each calendar quarter, rather than each fiscal quarter, as Form PF currently requires.[531] The SEC anticipates that these amendments will improve the consistency of reporting across different private fund advisers, across quarterly and annual filings, and across different regulatory forms,[532] which may improve the ability of regulators to analyze filing data across fund advisers and across different regulatory forms by resolving reporting errors and issues of data quality. These data analyses are important contributors to the SEC's and FSOC's efforts to assess systemic risk and develop a complete picture of private fund markets. The SEC anticipates that these improved reporting alignments may enhance the SEC's and FSOC's abilities to assess potential risks presented by private funds.[533] For example, as discussed above, academic research has used Form PF data and Form N–MPF data to study rule 2a–7 risk limits and implications of money market reforms.[534] Standardizing data across regulatory filings can lead to further industry insights from combined regulatory filing data, and these industry insights may improve systemic risk assessment and regulator investor protection efforts. However, as discussed above, because almost all large hedge fund advisers and large liquidity fund advisers already effectively file on a calendar quarter basis because their fiscal quarter ends on the calendar quarter, the SEC anticipates that these benefits will be marginal.[535]

Fourth, the amendments issue a series of revisions that impact several sections of Form PF, which will broadly enhance data quality, for example by potentially resolving reporting errors. These amendments will specify that reported percentages be rounded to the nearest one hundredth of one percent, provide consistent instruction for reporting of investment and counterparty exposures, provide consistent instruction on the reporting of long and short positions, and provide consistent instruction for reporting of derivative values.[536] The resulting improved data quality will improve the ability of the SEC and FSOC to evaluate market risk and measure industry trends, thereby increasing the efficiency with which regulatory responses are developed, improving systemic risk assessment and regulator programs to protect investors.

We did not receive specific comments on certain of these proposed amendments, such as the amended instructions to specify how private fund advisers determine the value of investment positions (including derivatives) and counterparty exposures.[537] Some commenters expressed support for the amendments to require advisers to report their long and short holdings on a disaggregated basis,[538] and other commenters opposed the requirements for more detailed disclosures of holdings.[539]

Certain changes made in response to commenters will enhance the benefits of these amendments. For example, one commenter stated that the definition of ''10-year bond equivalent'' specifies the expression of the value in the fund's base currency.[540] By revising the ''10-year bond equivalent'' definition to reference U.S. dollars, rather than the fund's base currency, resulting metrics will be reported in a common currency, which will enhance data quality and comparability purposes.[541]

Lastly, the amendments issue a series of additional revisions that will amend instructions related to temporary hardship exemptions, provide conformity with the CFTC's amendments to Form CPO–PQR (including those that specify when advisers that are also CPOs should complete particular sections of Form PF), and revise definitions of the terms EEA and G10 within Form PF.[542] The additional amendments updating instructions to the temporary hardship exemption to Form PF, by way of an amendment to 17 CFR 275.204(b)–1(f) under the Advisers Act, will make it easier to submit a temporary hardship exemption and will assist advisers in

[527] *See supra* section II.A.2.

[528] *Id.*

[529] *Id.*

[530] *Id.; see also, e.g.,* MFA Comment Letter II; Schulte Comment Letter.

[531] *See supra* section II.A.3.

[532] *Id.*

[533] While the amendments to general instructions associated with reporting timelines will primarily offer economic benefits associated with improvement in data quality and resolutions to data gaps, the amendments to reporting timelines will also provide a potential improvement to regulators' ability to evaluate markets for investor protection efforts and systemic risk assessment, in that they accelerate the provision of data from quarterly reporting. *See supra* section II.A.3. Moreover, as the amendments will make reporting timelines more consistent, there could be reduced costs associated with regulatory filings, as private fund advisers reduce their need to track differentiated calendar quarter and fiscal quarter data.

[534] *See supra* section IV.B.1.

[535] *See supra* section II.A.3. Specifically, and as discussed above, based on staff analysis of Form ADV data as of Dec. 2021, 99.2% of private fund advisers already effectively file on a calendar basis because their fiscal quarter or year ends on the calendar quarter or year end, respectively. The 0.8% of private fund advisers that have a non-calendar fiscal approach represents approximately 274 private funds, totaling $200 billion in gross asset value. *See supra* section II.A.3.

[536] *See supra* section II.D.

[537] *Id.*

[538] *Id.*

[539] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter. *See supra* section II.C.2.a.

[540] *Id.; see also* AIMA/ACC Comment Letter.

[541] *See supra* section II.D.

[542] *See supra* section II.E, Revised Instruction 18.

determining what constitutes a ''filed'' temporary hardship exemption.[543] These amendments may facilitate more successful submissions of temporary hardship exemptions by private fund advisers who require one, and may thereby benefit those advisers, and by extension their investors, by reducing costs. Similarly, by providing conformity with the CFTC's amendments to Form CPO–PQR, including those that specify when advisers that are also CPOs should complete particular sections of Form PF, and revising definitions associated with the terms EEA and G10, the amendments may reduce confusion for advisers filing Form PF, thereby reducing the burden of filing.[544] We did not receive comments on this aspect of the proposed changes.[545]

b. Amendments to Basic Information About the Adviser and the Private Funds It Advises

The amendments to section 1, which requires all private fund advisers to report information about the adviser and the private funds they manage, include revisions to section 1a (concerning basic identifying information),[546] revisions to section 1b (concerning all of a private fund adviser's private funds),[547] and revisions to section 1c (more specifically concerning all of a private fund adviser's hedge funds).[548] The changes will provide greater insight into all private funds' operations and strategies, and will further assist in assessing industry trends. This section discusses how the SEC believes the changes will thereby enhance the SEC's and FSOC's systemic risk assessment efforts and the SEC's efforts to protect investors by identifying areas in need of outreach, examination, or investigation. This will be accomplished in four key ways.

First, the changes will provide more prescriptive requirements to improve comparability across advisers and reduce reporting errors and issues of data quality by aligning data across filers and across regulatory filings, based on our experience with the form. This greater alignment is designed to improve the efficiency with which the SEC and FSOC evaluate market risk and measure industry trends, thereby increasing the efficiency with which regulatory responses are developed, improving systemic risk assessment and regulator programs to protect investors. For example, revisions to section 1a (relating to adviser reporting of identifying information for all private funds they advise) will revise instructions on the use of LEIs and RSSD IDs for advisers and related persons, and might help link data more efficiently between Form PF and other regulatory filings that use these universal identifiers.[549] Several revisions to section 1b (relating to adviser reporting of basic information for all private funds they advise) will modify instructions and might prevent advisers from inadvertently reporting different fund types on different regulatory filings (or, when different reporting on two different forms is appropriate, the revised instructions are designed to solicit the reason for differentiated reporting), facilitating more robust data analyses that use combined data from multiple regulatory forms.[550] Revisions to section 1c will require advisers to indicate which investment strategies best describe the reporting fund's strategies on the last day of the reporting period, addressing any ambiguity about how to report information if the reporting fund changes strategies over time.[551] The SEC believes these revisions to section 1, and others,[552] will improve the accuracy and reliability of Form PF data, thereby potentially improving the SEC's and FSOC's efforts to assess developing systemic risks and FSOC's efforts to assess broader financial instability, as well as potentially improving the SEC's efforts to protect investors by identifying areas in need of outreach, examination, or investigation.

While commenters who criticized these changes generally emphasized the costs of the changes, along with the overall costs of the amendments,[553] certain commenters also questioned the benefits. For example, one commenter opposed including more granular strategy categories stating that some proposed categories are not clear and may require advisers to make subjective decisions on how to report a fund's strategy that could result in inconsistent reporting.[554] While certain advisers may have to make certain subjective decisions, the amended strategy categories conform more closely to industry conventions than the current categories and will allow advisers to more accurately categorize their strategies. Any remaining ambiguity in these strategy categories will only mitigate the benefits of the resulting reporting, not eliminate the benefits.

Certain other commenters agreed with the benefits of certain proposed provisions. For example, one commenter supported an expanded use of LEI as a legal identifier in Form PF and stated that more comprehensive inclusion of LEI would create a more complete identification scheme for the Commissions.[555] Still other commenters suggested further revisions, and certain changes made in response to those commenters will enhance these benefits. For example, some commenters stated that proposed questions on withdrawal and redemption rights did not address how to report a fund with multiple types of redemption rights.[556] In response, we are modifying the question to ask for the interval on which withdrawals or redemptions are ''most commonly'' permitted (*i.e.,* with respect to most investors). We also encourage an adviser to report any additional details on a fund's withdrawal or redemption schedule in response to Question 4, as appropriate. This will likely improve comparability across advisers and reduce reporting errors and issues of data quality. Still other amendments did not receive specific comments, such as the amendment requiring an adviser to identify the fund type for a reporting fund as ''other'' and explaining why the

[543] *See supra* section II.E.

[544] *See supra* section II.E, Revised Instruction 18.

[545] *See supra* section II.E.

[546] *See supra* section II.B.1.

[547] *See supra* section II.B.2.

[548] *See supra* section II.B.3.

[549] *See supra* section II.B.1. For example, the reporting of a fund's and its adviser's LEI is consistent with the way fund relationships are reported in the Global LEI system. *See, e.g.,* LEI ROC, *Policy on Fund Relationships and Guidelines for the Registration of Investment Funds in the Global LEI System* (May 20, 2019), *available at https://www.leiroc.org/publications/gls/roc_20190520-1.pdf.*

[550] *See supra* section II.B.2. For example, the Division of Investment Management relies on Form PF and Form ADV filings in providing quarterly summaries of private fund industry statistics and trends. *See, e.g.,* SEC, Division of Investment Management, *Private Fund Statistics* (Aug. 21, 2021), *available at https://www.sec.gov/divisions/investment/private-funds-statistics.shtml.*

[551] *See supra* section II.B.3.

[552] Other revisions that will provide this benefit include revising reporting of regulatory versus net assets under management; reporting of assumptions the adviser makes in responding to questions on Form PF; reporting of types of fund; reporting of master-feeder arrangements, internal/external private funds, and parallel fund structures; reporting of monthly gross and net asset values; reporting of the value of unfunded commitments; reporting on the value of borrowing activity; reporting of fair value hierarchy; reporting of beneficial ownership; reporting of fund performance; more granular reporting of hedge fund strategies; more granular reporting of hedge fund counterparty exposures including identification of counterparties representing a fund's greatest exposure; and more granular reporting of hedge fund trading and clearing mechanisms. *See supra* section II.B.

[553] *See infra* section IV.C.2.

[554] *See supra* section II.B.3; *see also* MFA Comment Letter II.

[555] *See supra* section II.B.1; *see also* GLEIF Comment Letter.

[556] *See supra* section II.B.2; *see also, e.g.,* MFA Comment Letter II; SIFMA Comment Letter.

fund does not qualify for any of the other options.[557]

Second, the amendments will expand the data collected by the forms, thereby facilitating the Commissions and FSOC to assess newly emerging areas of potential systemic risk. These expanded areas of reporting broadly capture key trends in (i) private fund advisers' ownership structures, and (ii) private fund advisers' investment and trading strategies, including increasing exposures to new asset classes, changing exposures across different categories of counterparties, and increasing use of financial tools for increasing fund performance.

With respect to updated reporting on ownership structures, as discussed above, interconnected ownership structures have inherent risks of spillovers in losses, as losses in a master fund or underlying investment of a fund of funds cause losses in connected funds as well, and so the enhanced data on detailed ownership structures from the final amendments are designed to improve systemic risk assessment efforts.[558] Improved data will also contribute to efforts to protect investors from conflicts of interest and other sources of potential harm.[559] The types of enhancements to Form PF's data on interconnected ownership structures include, for example, requiring advisers to provide LEIs for themselves and any of their related persons, such as reporting funds and parallel funds,[560] and expanding the required reporting detail on the value of the reporting fund's investments in funds of funds.[561] Similar to the amendments to general instructions, the SEC believes that these revisions will improve measurement of these complex ownership structures. The SEC believes this will potentially improve the SEC's and FSOC's efforts to assess developing systemic risks and FSOC's efforts to assess broader financial instability, as well as potentially improve the SEC's efforts to protect investors from conflicting arrangements and identify other areas in need of outreach, examination, or investigation.[562]

Many revisions will also keep Form PF filings up to date with key developing trends among private fund advisers' investing and trading practices. These revisions will improve consistency of reporting of modern private fund issues across fund advisers, provide more complete and accurate information on developing trends, and improve the SEC's and FSOC's abilities to effectively and efficiently assess new systemic risks and other potential sources of investor harm, as well as inform the SEC's and FSOC's broader views on the private fund landscape.

For example, in Form PF section 1c, the amendments will require hedge funds to report whether their investment strategy includes digital assets,[563] which are a growing and increasingly important area of hedge fund strategy.[564] The amendments will therefore help the SEC and FSOC to assess new sources of potential systemic risk and develop regulatory responses, and will further allow the SEC to analyze new areas of potential investor harm to determine any necessary outreach, examination, or investigation.

As another example, the amendments will introduce several questions on counterparty exposures, corresponding to both CCP exposures and bilateral counterparty (*i.e.,* non-CCP) exposures. These additions to Form PF include requiring advisers to report hedge fund borrowing, lending, and collateral with respect to transactions involving both their bilateral counterparties and CCPs, requiring reporting of hedge fund derivative and repo activity that was cleared by a CCP (as well as activity not cleared by a CCP), and instructing advisers on what exposures to net.[565] There are two economic considerations associated with counterparty exposure reporting on Form PF. First, bilateral exposures and CCP exposures have different risk profiles, with CCPs offering risk reduction mechanisms and other economic benefits by netting trading across counterparties and across different assets within an asset class or by centralizing clearance and settlement activities.[566] The final amendments are designed to help Form PF provide insight into relative trends in bilateral trading versus central counterparty trading and resulting systemic risks from counterparty exposures. Second, while CCPs reduce the systemic risk associated with the failure of any single hedge fund or other private fund, the failure of a large CCP itself could potentially represent a substantial systemic risk event in the future.[567] While a systemic risk event such as the failure of a CCP has never occurred in the United States, CCPs in other countries have failed,[568] and the final amendments are designed to help Form PF provide new insights into the potential for such systemic risk events in the future. FSOC has also designated many CCP institutions as ''systemically important,'' [569] and recommends that regulators continue to coordinate to evaluate threats from both default and non-default losses associated with CCPs.[570]

As a final example, we are adopting amendments that require advisers to report additional performance-related information if the adviser calculates a market value on a daily basis for any position in the reporting fund's portfolio.[571] These include, among other items, the reporting fund's volatility of the natural log of the daily ''rate of return'' for each month of the reporting period.[572] Investors will benefit from systemic risk assessment efforts and investor protection efforts facilitated by these reporting items. For example, allowing the Commission and FSOC to compare volatility across different fund types to identify market trends (*e.g.,* volatility of a specific fund type) will help the Commission and FSOC verify which strategies are the most volatile and therefore pose the greatest default risk to bank and broker/dealer counterparties. Comparing volatility data on Form PF and risk metric data on Form PF, such as VaR (Value-at-Risk) data, will also help the Commission to

[557] *See supra* section II.B.2.

[558] *See supra* section IV.C.1.a.

[559] *Id.*

[560] *See supra* section II.B.1.

[561] *See supra* section II.B.2.

[562] *See supra* section IV.C.1.a.

[563] *See supra* section II.B.3.

[564] *See, e.g.,* AIMA, PWC & Elwood Asset Management, Annual Global Crypto Hedge Fund Report (2023), *available at https://www.pwc.com/gx/en/news-room/press-releases/2023/pwc-2023-global-crypto-hedge-fund-report.htmlhttps://www.pwc.com/gx/en/news-room/press-releases/2023/pwc-2023-global-crypto-hedge-fund-report.html* (concluding that almost a third of traditional hedge funds were investing in such assets in 2023, with average allocations of 7%, representing increases relative to 2021); AIMA, PWC & Elwood Asset Management, 3rd Annual Global Crypto Hedge Fund Report (2021), *available at https://www.aima.org/educate/aima-research/third-annual-global-crypto-hedge-fund-report-2021.html* (concluding that approximately a fifth of hedge funds were investing in such assets in 2021, with on average 3% of their total hedge fund assets under management invested, and 86% of those hedge funds intended to deploy more capital into this asset class by the end of 2021); *see also supra* section II.B.3.

[565] *See supra* section II.B.3.

[566] Siro Aramonte & Wenqian Huang, *Costs and Benefits of Switching to Central Clearing,* BIS Q. Rev. (Dec. 2019), *available at https://www.bis.org/publ/qtrpdf/r_qt1912z.htm;* Albert J. Menkveld & Guillaume Vuillemey, *The Economics of Central Clearing,* 13 Ann. Rev. Fin. Econ. 153 (2021).

[567] *Id.*

[568] For example, the Hong Kong Futures Guarantee Corporation failed during the stock market crash of 1987. *See* Menkveld & Vuillemey, *supra* footnote 566.

[569] Fin. Stability Oversight Council, 2012 Annual Rep., Appendix A, *available at https://home.treasury.gov/system/files/261/2012-Annual-Report.pdf.*

[570] *Id.* at 14.

[571] *See supra* section II.B.2.

[572] *Id.*

detect misleading uses of risk metrics by funds in disclosures to investors.

The SEC therefore believes these revisions, and others like them,[573] will help the SEC and FSOC better understand the modern landscape of the private fund industry, thereby potentially improving the SEC's and FSOC's efforts to assess developing systemic risks and FSOC's efforts to assess broader financial instability, as well as potentially improving the SEC's efforts to protect investors by identifying areas in need of outreach, examination, or investigation.

Some commenters questioned the benefits of these types of amendments. For example, some commenters stated that disclosure of counterparty exposures is of limited value.[574] However, we continue to believe that this additional information is important to understanding counterparty risk exposure, and counterparty risk exposures represent substantial sources of systemic risk.[575] Certain others of these proposed amendments did not receive significant comment on their proposed benefits. For example, the amendments requiring additional performance-related information if the adviser calculates market value did not receive significant comment. One commenter recommended requiring volatility measurements over longer periods, such as quarterly or annually, stating that requiring daily measurements would result in a smaller population size and less meaningful information.[576] As discussed above, higher frequency volatility information is important because significant volatility swings that occur over a short timeframe may not be discernible from quarterly or annual data but can pose systemic risk.[577] Further, receiving higher frequency volatility data will give more context to a fund's reported monthly returns and will allow us to assess risk-adjusted returns.[578] In still other cases, the benefits from the final amendments will be enhanced by changes made in response to commenters. For example, one commenter recommended, for reporting of certain drawdown metrics associated with days with a negative daily rate of return, changing reporting of amount in base currency to percent in base currency, and the final amendments implement this change to be more reflective of industry practice, and in turn improve data quality.[579]

Third, there are revisions that will expand the scope of certain questions from only covering qualifying hedge funds advised by large hedge fund advisers to covering all hedge funds advised by any private fund adviser. By expanding the universe of private funds that are covered by several questions, the amendments will enhance the SEC's and FSOC's ability to conduct broad, representative measurements regarding the private fund industry. For example, the amendments will require all advisers to indicate whether the reporting fund is an open-end private fund in Question 10(a) or a closed-end private fund in Question 10(b).[580] Because the activities of private fund advisers may differ significantly depending on their size, this enhanced coverage will potentially enhance regulators' abilities to obtain a representative picture of the private fund industry and lead to more robust conclusions regarding emerging industry trends and characteristics. The SEC believes these amendments, and others,[581] will enhance regulators' picture of the private fund industry, thereby potentially improving the SEC's and FSOC's efforts to assess developing systemic risks and FSOC's efforts to assess broader financial instability, as well as potentially improving the SEC's efforts to protect investors by identifying areas in need of outreach, examination, or investigation.

Some commenters questioned these benefits. For example, one commenter asserted that the data would be of limited benefit for systemic risk monitoring because of the inclusion of data from smaller funds.[582] However, we continue to believe that a private fund of any size that provides for withdrawal or redemption rights may be affected by increased investor withdrawals during certain market events and/or vulnerable to failure as a result of investor redemptions, and so the additional data will be relevant for assessing broader systemic risk, for example by allowing the Commissions and FSOC to assess the prevalence of the exercise of withdrawal and redemption rights to identify potential patterns among affected funds that may signal stress at a particular fund or across many funds.[583] Information on withdrawal and redemption rights from all private funds, including smaller private funds or funds that are not included in the definition of a ''hedge fund,'' will improve FSOC's ability to monitor potential systemic risk and support the Commissions' investor protection efforts.

One commenter supported the proposed amendments and agreed with the potential benefits, stating that expanding the classes of private funds that are required to disclose withdrawal and redemption rights would allow FSOC to better identify systemic risks, particularly resulting from market events.[584] Lastly, certain changes will streamline reporting and reduce the reporting burden by removing certain questions where other questions provide the same or superseding information. For example, the amendments will remove current Question 19, which requires advisers to hedge funds to report whether the hedge fund has a single primary investment strategy or multiple strategies, and will also remove current Question 21, which requires advisers to hedge funds to approximate what percentage of the hedge fund's net asset value was managed using high frequency trading strategies.[585] The SEC believes that these revisions will benefit advisers and investors by directly lowering the costs and reducing part of the burden on advisers of completing Form PF filings.[586] Commenters generally supported amendments that eliminate questions and streamline reporting requirements.[587]

c. Amendments to Information About Hedge Funds Advised by Large Private Fund Advisers

The changes to section 2 will provide greater insight into operations and strategies into hedge funds advised by large private fund advisers specifically, and will also assist in assessing broader hedge fund industry trends. This section

[573] Other revisions that will provide this benefit include the reporting of withdrawal and redemption rights; reporting of other inflows and outflows; more granular reporting of hedge fund strategies; more granular reporting of hedge fund counterparty exposures including identification of counterparties representing a fund's greatest exposure; and more granular reporting of hedge fund trading and clearing mechanisms. *See supra* section II.B.

[574] *See supra* section II.B.3; *see also, e.g.,* AIMA/ACC Comment Letter.

[575] *See supra* footnotes 565 through 570 and accompanying text.

[576] *See supra* section II.B.2; *see also* CFA Institute Comment Letter.

[577] *See supra* section II.B.2.

[578] *Id.*

[579] *Id.; see also* CFA Institute Comment Letter.

[580] *See supra* section II.B.2.

[581] The revisions to reporting of base currency will provide similar benefits. *See supra* section II.B.

[582] *See supra* section II.B.2; *see also* Schulte Comment Letter.

[583] *See supra* section II.B.2.

[584] *See supra* section II.B.2; *see also* Fact Coalition Comment Letter.

[585] *See supra* section II.B.3.

[586] These benefits from streamlined reporting and reduced reporting burden will be offset by increased costs associated with the additional and more granular detail that will be required on Form PF under the amendments. *See infra* sections IV.C.2, V.C.

[587] *See supra* section II.B.3; *see also, e.g.,* MFA Comment Letter II; SIFMA Comment Letter; Better Markets Comment Letter.

discusses how the SEC believes the changes will thereby enhance the SEC's and FSOC's investor protection and systemic risk assessment efforts. This will be accomplished in three key ways.

As with section 1, first, the changes will provide more prescriptive requirements to improve comparability across advisers and reduce reporting errors and issues of data quality, based on experience with the form. This will be accomplished by standardizing reporting of information across different advisers and across different regulatory filings. For example, the amendments to current Question 30 (on qualifying hedge fund exposures to different types of assets) will replace the existing complex table in current Question 30 with a redesignated Question 32 with reporting instructions that will use a series of drop-down menu selections and provide additional narrative reporting instructions and additional information on how to report exposures.[588] Similarly, advisers to qualifying hedge funds will now be required to report the 10-year zero coupon bond equivalent for all sub-asset classes with interest rate risk, rather than providing advisers with a choice to report duration, WAT, or an unspecified 10-year equivalent.[589] Several revisions (relating to adviser reporting of basic information for all hedge funds that it advises) will revise instructions relating to reporting of adjusted long and short exposures and market factor effects on a hedge fund's portfolio.[590] These revisions can potentially prevent, for example, data errors associated with reporting of long and short components of a portfolio or discrepancies across advisers in their choices of which market factors to report (as Form PF currently allows advisers to omit a response to any market factor that they do not regularly consider in formal risk management testing).[591] As another example, the changes will provide for a new sub-asset class in investment exposure reporting for ADRs, in line with how ADRs are reported on the CFTC's Form CPO–PQR, potentially improving assessment of currency risk across regulatory filings.[592] As a final example, the changes will revise reporting for positions held physically, synthetically, or through derivatives and indirect exposure, and will require reporting turnover on a per fund basis instead of in the aggregate as well as providing for more granular reporting of turnover.[593] The SEC believes these revisions, and others,[594] will align Form PF data across filers, thereby potentially improving the efficiency with which the SEC and FSOC evaluate market risk and measure industry trends, thereby increasing the efficiency with which regulatory responses are developed, improving systemic risk assessment and regulatory programs to protect investors.

Several changes in response to commenters will either enhance these benefits or will provide substantially the same benefits relative to the proposal but at reduced burden to advisers. For example, in response to commenters, under the final amendments advisers are permitted to report an entirely indirectly held entity position in one sub-asset class and instrument type that best represents the sub-asset class exposure of the indirectly held entity, unless the adviser would allocate the exposure of the indirectly held entity more granularly under its own internal methodologies and conventions of its service providers.[595] This modification balances the importance of obtaining more accurate and granular data with a reporting standard that is less burdensome for advisers than the proposed standard. Similarly, in the final amendments, in response to commenters we are modifying the ''10-year bond equivalent'' definition to reference U.S. dollars, rather than the fund's base currency, so that advisers will not be required to perform any additional exchange conversions.[596] As a final example, with respect to market factor reporting, commenters suggested that the proposal was unclear in certain questions as to whether an adviser is required to ''look through'' the fund's investments.[597] In response, we are adding an instruction that when reporting exposures to changes in market factors for indirect positions, an adviser may use reasonable estimates that best represent the exposure to the market factor, consistent with the adviser's internal methodologies and conventions of service providers.[598]

Many commenters also agreed with the benefits of certain proposed amendments. For example, commenters supported the amendments to require hedge fund advisers to report their long and short holdings on a disaggregated basis, or stated that requiring private fund advisers to report both long and short positions will allow FSOC to have a complete picture of the risk exposure across private funds, or stated that allowing advisers to aggregate their positions between physically held and synthetically held positions can make it difficult to understand the impact of hedge fund activity especially during periods of market instability.[599] Several of these amendments did not receive comments. For example, we did not receive comments on many aspects of the amendments to redesignated Question 32.[600]

Second, the changes will help Form PF provide greater insight into newly emerging areas of risk, including increasing exposures to new asset classes, changing exposures across different categories of counterparties, and changing risk management practices (such as changing practices around posting of collateral). The SEC believes these changes will help Form PF more completely and accurately capture information relevant to ongoing trends in the private fund industry. For example, in addition to the more general investment strategy questions in section 1c described above,[601] section 2b will

[588] *See supra* section II.C.2.

[589] *Id.*

[590] *See supra* sections II.C.2.a; II.C.2.c.

[591] *Id.* For example, higher quality data on short positions can facilitate more accurate and timely identification of significant market participants during periods of volatility related to shorting activity, such as the Jan. 2021 ''meme stock'' episodes. *See, e.g.,* SEC, Staff Rep. on Equity and Options Market Structure Conditions in Early 2021 (Oct. 14, 2021), *available at https://www.sec.gov/files/staff-report-equity-options-market-struction-conditions-early-2021.pdf.*

[592] *See supra* section II.C.2.a.

[593] As discussed above, when monitoring funds' activities during recent market events like the Mar. 2020 COVID–19 turmoil, the existing aggregation of U.S. Treasury securities with related derivatives did not reflect the role hedge funds played in the U.S. Treasury market. *See supra* sections II.C.2.a, IV.B.1. Also during the COVID–19 market turmoil, FSOC sought to evaluate the role hedge funds played in disruptions in the U.S. Treasury market by unwinding cash-futures basis trade positions and taking advantage of the near-arbitrage between cash and futures prices of U.S. Treasury securities. Because the existing requirement regarding turnover reporting on U.S. Treasury securities is highly aggregated, the SEC staff, during retrospective analyses on the Mar. 2020 market events, was unable to obtain a complete picture of activity relating to long treasuries and treasury futures. *See supra* sections II.C.2.d, IV.B.1.

[594] Other revisions that will provide this benefit include the amendments revising reporting of reportable sub-asset classes, including those for certain categories of listed equity securities, repos, asset-backed securities and other structured products, derivatives, and cash and commodities; revising reporting of open and large position reporting; revising reporting of counterparty exposures including reporting of significant counterparties; revising currency reporting; requiring significant country and industry exposure; requiring additional reporting on fund portfolio risk profiles; requiring more granular reporting of investment performance by strategy; amending reporting of portfolio liquidity; and amending reporting of financing liquidity. *See supra* section II.C.

[595] *See supra* section II.C.2.a.

[596] *Id.*

[597] *See supra* section II.C.2.c; *see also* MFA Comment Letter III.

[598] *See supra* section II.C.2.a.

[599] *Id.; see also* AFREF Comment Letter I; Better Markets Comment Letter.

[600] *See supra* section II.C.2.a.

[601] *See supra* section IV.C.1.b.

require large advisers to qualifying hedge funds to report their total exposures to digital assets.[602] As another example, large advisers to qualifying hedge funds will be required to report exposures to additional commodity sub-asset classes (*e.g.,* other (non-gold) precious metals, agricultural commodities, and base metal commodities).[603] They will also be required to report all other counterparties (by name, LEI, and financial institution affiliation) to which a fund has net mark-to-market exposure after collateral that equals or is greater than either (1) five percent of a fund's net asset value or (2) $1 billion, facilitating regulators' abilities to understand the impact of a particular counterparty failure like those that occurred during the 2008 financial crisis and in the period since (*e.g.,* the failure of MF Global in 2011).[604] Advisers will also be required to report certain of their exposures to CCPs,[605] and will be required to report each CCP (or other third party) holding collateral in respect of cleared exposures in excess of five percent of the fund's net asset value, or $1 billion.[606]

As a final example, advisers will be required to determine adjusted exposure for each ''sub-asset'' using a specified methodology, as proposed. This methodology will include, among other specifications, netting positions that have the same underlying reference asset across instrument type, including positions held indirectly through another entity such as ETFs and other exchange traded products.[607] These amendments will also include defining ''exchange traded product'' to better facilitate exchange traded product and ETF exposure reporting. These types of funds are important avenues of investing for many types of investors but can represent different systemic risks than other types of investments, potentially increasing certain types of risk and decreasing other types of risk.

As discussed above, these (and other) new granular reporting requirements will represent new possible sources of systemic risk for the SEC and FSOC to evaluate, and also new areas of focus for the SEC's regulatory outreach, examination, and investigation.[608] The SEC believes these revisions, and others,[609] will improve the SEC's and FSOC's efforts to assess developing systemic risks and FSOC's efforts to assess broader financial stability, as well as potentially improve the SEC's efforts to protect investors by identifying areas in need of outreach, examination, or investigation.

Some commenters questioned or were skeptical of these benefits. For example, one commenter indicated that existing data sources, such as existing Form PF, Form 13F and 13H, and CFTC Form CPO–PQR, already allow the Commissions to obtain granular information about a fund's holdings with respect to the new sub-asset classes.[610] As discussed above, we have identified information gaps in the data reported on the existing Form PF based on our experience, and we are unable to determine the full extent of a fund's exposure because the different types of exposures are combined.[611] The final amendments will generate the intended benefits described above.[612]

Lastly, the amendments will remove certain questions where other questions provide the same or superseding information, which the SEC believes will streamline reporting and reduce reporting burden. For example, the changes will remove section 2a entirely, based on a determination that the aggregated information in section 2a is redundant to information required to be reported in other sections,[613] and will remove the requirement from Question 38 for advisers to report the percentage of the total amount of collateral and other credit support that a fund has posted to counterparties that may be re-hypothecated.[614] The SEC believes that these revisions, and others,[615] will directly lower the costs and reduce the burden to advisers of completing Form PF filings. Commenters who discussed these proposed amendments agreed that there would be benefits from reducing the burden by eliminating questions and streamlining reporting requirements.[616]

2. Costs

The amendments to Form PF will lead to certain additional costs for private fund advisers. Any portion of these costs that is not borne by advisers will ultimately be passed on to private funds' investors. These costs will vary depending on the scope of the required information, which is determined based on the size and types of funds managed by the adviser as well as each fund's investment strategies, including choices of asset classes and counterparties. These costs are quantified, to the extent possible, by examination of the analysis in section V.C.

The SEC anticipates that the costs to advisers associated with Form PF will be comprised of both direct compliance costs and indirect costs. Direct costs for advisers will consist of internal costs (for compliance attorneys and other non-legal staff of an adviser, such as computer programmers, to prepare and review the required disclosure) and external costs (including filing fees as well as any costs associated with outsourcing all or a portion of the Form PF reporting responsibilities to a filing agent, software consultant, or other third-party service provider).[617]

The SEC believes that the direct costs associated with the final amendments will be most significant for the first updated Form PF report that a private fund adviser will be required to file because the adviser will need to

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[602] *See supra* section II.C.2.a.

[603] Id.

[604] *See supra* section II.C.2.a, footnote 360 and accompanying text.

[605] *See supra* section II.C.2.b.

[606] *See supra* section II.C.2.d.

[607] *See supra* section II.C.2.a.

[608] *See supra* section IV.C.1.b. For example, the SEC believes the addition of a base metal commodities sub-asset class will allow for identification of large players in the base metals market (such as those impacted by the Mar. 2022 ''nickel squeeze,'' during which the price of nickel rose unusually steeply and rapidly in response to commodity price increases caused by Russia's invasion of Ukraine). *See supra* footnote 323.

[609] Other revisions that will provide this benefit include revising reporting for positions held physically, synthetically, or through derivatives and indirect exposure; revising reportable sub-asset classes, including those for certain categories of listed equity securities, repos, asset-backed securities and other structured products, derivatives, and other cash and commodities; further revising reporting of counterparty exposures including reporting of significant counterparties (in addition to the revisions to CCP exposures); revising currency reporting; requiring more granular reporting of turnover; requiring significant country and industry exposure; requiring additional reporting on fund portfolio risk profiles; requiring more granular reporting of investment performance by strategy; requiring new reporting on portfolio correlation; amending reporting of portfolio liquidity; and amending reporting of financing liquidity. *See supra* section II.C.

[610] *See supra* section II.C.2.a; *see also* SIFMA Comment Letter.

[611] *See supra* section II.C.2.a. We discuss the costs of these amendments, including comments on the proposed amendments, below. *See infra* section IV.C.2.

[612] Other commenters were opposed to these amendments, but primarily on the basis of costs of the updated reporting. *See supra* section II.C.2.b; *see also* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter. We discuss the costs of these amendments, including comments on the proposed amendments, below. *See infra* section IV.C.2.

[613] *See supra* section II.C.1.

[614] *Id.*

[615] Other revisions that will provide this benefit include consolidating Question 47 into Question 36; removing the requirement from Question 38 for advisers to report the percentage of the total amount of collateral and other credit support that a fund has posted to counterparties that may be re-hypothecated; and requiring reporting turnover on a per fund basis instead of in the aggregate. *See supra* section II.C.

[616] *See supra* sections II.C.1, II.C.2.b; *see also, e.g.,* MFA Comment Letter II; SIFMA Comment Letter; Better Markets Comment Letter.

[617] *See* section V.C. (for an analysis of the direct costs associated with the new Form PF requirements for quarterly and annual filings).

familiarize itself with the new reporting form and may need to configure its systems to gather the required information efficiently. In subsequent reporting periods, the SEC anticipates that filers will significantly lower costs because much of the work involved in the initial report is non-recurring and because of efficiencies realized from system configuration and reporting automation efforts accounted for in the initial reporting period. This is consistent with the results of a survey of private fund advisers, finding that the majority of respondents identified the cost of subsequent annual Form PF filings at about half of the initial filing cost.[618]

The SEC anticipates that the amendments aimed at improving data quality and comparability will impose limited direct costs on advisers given that advisers already accommodate similar requirements in their current Form PF reporting and can utilize their existing capabilities for preparing and submitting an updated Form PF. The SEC expects that most of the costs will arise from the requirements to report additional and more granular information on Form PF. These direct costs will mainly include an initial cost to set up a system for collecting, verifying additional more granular information, and limited ongoing costs associated with periodic reporting of this additional information.[619] We believe that the amendment to 17 CFR 275.204(b)–1(f) under the Advisers Act will have minimal costs associated with it, as the amendment only makes it easier to submit a temporary hardship exemption and assists advisers in determining what constitutes a ''filed'' temporary hardship exemption.[620] As discussed in the benefits section, the SEC believes that part of the costs to advisers arising from the amendments will be mitigated by the cost savings resulting from reduced ambiguities and inefficiencies that currently exist in the reporting requirements, as this may reduce the amount of time and effort required for some advisers to prepare and submit Form PF information.[621]

Indirect costs for advisers will include the costs associated with additional actions that advisers may decide to undertake in light of the additional reporting requirements on Form PF. Specifically, to the extent that the amendments provide an incentive for advisers to improve internal controls and devote additional time and resources to managing their risk exposures and enhancing investor protection, this may result in additional expenses for advisers, some of which may be passed on to the funds and their investors.

Commenters also identified other indirect costs in the form of unintended effects, which we agree may occur. For example, one commenter stated that requirements in Form PF to use a particular financial identifier may increase costs and reduce innovation and competition among financial identifier providers.[622] However, we do not think this effect is likely to occur, because Form PF continues to not require an adviser to obtain or use LEI or any other particular financial identifier (other than private fund identification numbers for reporting funds), as our amendments provide only that any identifier that does not meet the definition of ''LEI'' may not be substituted for an LEI where a question requests an LEI.[623] Form PF continues to permit advisers to use other financial identifiers elsewhere on Form PF where the reporting of LEI is either not specified or not required.[624] Therefore, financial identifier providers will not likely experience any reduction in their incentives to innovate or compete.

Some commenters stated that there will be substantial burden including initial set-up costs, external costs, and ongoing costs associated with amending Form PF.[625] These commenters also stated that the Proposing Release economic analysis understated the costs of the amendments.[626] Several of the changes to the final amendments relative to the proposal are in response to commenter concerns on costs. Specifically, the final amendments have removed certain questions that were proposed and revised other questions in order to reduce their burden without compromising the goals of the Commissions and FSOC in improving the information received on the form for purposes of their systemic risk reviews. For example, we are revising certain questions related to exposures to instruct advisers to select the exposure that ''best represents'' the indirect investment of the reporting fund, based on commenter statements that obtaining information about a fund's indirect exposures through investments in other funds could be difficult or burdensome.[627] As a second example, we are also not adopting a proposed question on portfolio correlations in response to comments that the proposed portfolio calculation questions would have been complex and burdensome to calculate.[628] As a third example, one commenter stated that for quarterly filers who have a fiscal year ending in

[618] *See* Kaal, *supra* footnote 487.

[619] Based on the analysis in section V.C, initial costs associated with filing the first updated Form PF report are estimated to increase by $5,820 for smaller private fund advisers, $20,190 for large hedge fund advisers, $10,592 for large liquidity fund advisers, and $10,647 for large private equity fund advisers. These figures are calculated as the cost of filing under the amended form minus the cost of filing prior to the amendments for each category of adviser. *See* Table 6. Direct internal compliance costs associated with the amendments are estimated at $2,247 annually for smaller private fund advisers. Direct internal compliance costs associated with the amendments are estimated at $8,346 per quarterly filing or $33,384 annually for large hedge fund advisers. Direct internal compliance costs associated with the amendments are estimated at $5,136 per quarterly filing or $20,544 annually for large liquidity fund advisers. Direct internal compliance costs associated with the amendments are estimated at $4,815 annually for large private equity fund advisers. These figures are calculated as the cost of filing under the amendments minus the cost of filing prior to the amendments for each category of adviser. *See* Table 7. It is estimated that there will be no additional direct external costs and no changes to filing fees associated with the amendments. *See* Table 9. The SEC anticipates that there may be additional first-time filing costs for filers who do not currently file on a calendar quarter basis, but that these costs are likely to be small and not likely to impact subsequent filings beyond the first. As discussed above, a 2018 industry survey of large hedge fund advisers found filing costs that ranged from 35% to 72% higher than SEC cost estimates. These industry cost estimates would therefore suggest costs associated with the changes to Form PF that are potentially 35% to 72% higher than those estimated here. *See* MFA Letter to Chairman Clayton, *supra* footnote 364, at 3. However, a 2015 survey of SEC-registered investment advisers to private funds affirmed the SEC's cost estimates for smaller private fund advisers' Form PF compliance costs, and found that the SEC overestimated Form PF compliance costs for larger private fund advisers. These academic literature cost estimates would therefore suggest that the costs associated with the changes to Form PF estimated here are potentially conservatively large. *See* Kaal, *supra* footnote 487. We were persuaded by commenters who asserted that the proposed burdens underestimated the time and expense associated with the proposed amendments. To address commenters' concerns and recognizing the changes from the proposal, we have revised the estimates as reflected here and below. *See infra* section V.C.

[620] *See supra* section II.E.

[621] The final amendments also seek to limit unnecessary costs by avoiding redundancies between new questions and current Questions. For example, the SEC will remove current Question 22, as it would be redundant in light of the expanded turnover reporting. *See supra* footnote 385.

[622] *See supra* section II.B.1; *see also* Bloomberg Comment Letter.

[623] *See supra* section II.B.1.

[624] *Id.*

[625] *See, e.g.,* MFA Comment Letter III; AIMA/ACC Comment Letter; MFA/NAPFM Comment Letter.

[626] *Id.* The Proposing Release economic analysis' quantified costs were based on compliance cost estimates from the Proposing Release PRA analysis. As discussed above, industry and academic literature from 2015–2018 has varied in its findings on whether SEC's past PRA analysis estimates of Form PF compliance costs have historically been overstated or understated. To address commenters' concerns and recognizing the changes from the proposal, we are revising the estimates as reflected here and below. *See infra* section V.C; *see also supra* footnote 619.

[627] *See supra* sections II.A.2, II.C.2.

[628] *See supra* section II.C.2.

a non-calendar quarter month, the proposed instructions do not specify the procedure for a filer who, during the transition from fiscal to calendar quarter reporting, would otherwise be required to report twice in one calendar quarter.[629] In response, we are requiring that such filers transition to the new timing requirement by their first calendar quarter-end filing for the first full quarterly reporting period after the compliance date.[630] As a final example, we are permitting the use of RFACV and GRFACV in reporting certain questions related to asset values in Section 1b, concerning all private funds.[631] Permitting an adviser to report GRFACV or RFACV will reduce burden associated with reporting of valuation data on a monthly basis.[632]

However, there were certain proposed amendments that commenters criticized as burdensome but are being adopted largely as proposed. Each of these amendments is being adopted either because costs will be limited, because benefits will be substantial, or both. For example, commenters criticized the prescribed methodology for calculating netted exposure as burdensome as well as the need to identify relevant sub-asset classes and the need to measure these exposures on a monthly basis.[633] However, burden in the case of sub-asset classes will likely be limited, because advisers will generally only need to make the relevant determination of sub-asset classes once, with ongoing monitoring (and any reclassifications) relatively limited. Further, because a fund may use cross counterparty netting consistent with information reported by the fund internally for purposes of determining adjusted exposure, the adjusted exposure reporting will likely not be significantly burdensome, particularly for funds using common aggregator protocols.[634] As another example, some commenters opposed the requirement to provide additional detail regarding counterparty exposure and state that the information would be burdensome and costly to obtain.[635] For reasons discussed above,[636] we continue to believe that disaggregated counterparty exposure is important to systemic risk monitoring efforts, and will not be significantly burdensome to produce as we understand knowledge of counterparties to be a component of a fund's risk management practices. As a final example, one commenter stated that the requirement to report information expressed as a percentage to the nearest one hundredth of one percent will significantly increase the costs and additional burdens for reporting advisers.[637] However, as discussed above, percentages rounded to the nearest one hundredth of one percent will allow the Commissions to obtain and analyze more precise information that may otherwise be obscured, for example given that one one-hundredth of one percent can represent a meaningful dollar amount depending on the size of the private fund. And, while we recognize that this may not be the case for smaller funds, when such amounts are taken together for a large group of smaller funds, the aggregate amount across the fund group can represent a meaningful dollar amount for data analysis purposes.[638] However, given commenters' perspectives, we have increased our assessment of the incremental direct costs of the final amendments relative to the proposal, even after revising certain final amendments and questions relative to the proposal in order to reduce incremental burden.[639]

However, these costs must be analyzed alongside the important benefits that will accrue, as receiving exposure data on a monthly basis will allow us to better understand interim changes in exposures that may be relevant to systemic risk assessment that are not visible from the existing quarterly data, which may enhance the measurement of trends that may indicate systemic risk. Receiving these data on a monthly basis will also improve the Commissions' ability to compare netted exposures with other monthly reported data, such as redesignated Question 23, relating to fund performance reported by all private funds.[640] Being able to compare data on a monthly basis with other data at the same frequency is important for systemic risk assessment and to support investor protection efforts.[641]

Some commenters argued that the heightened compliance costs of Form PF may be particularly burdensome for small firms.[642] As a result, the final amendments may represent a barrier to entry for smaller advisers who cannot meet the compliance costs or who cannot compete after passing those costs on to investors. To the extent any smaller advisers either exit or forgo entry in response to these compliance costs, competition would be negatively affected. However, comments were made in the context of the proposal, and the final amendments reduce many of the costs of compliance relative to the proposal.[643] Therefore, these effects may be mitigated, but may nonetheless occur.

One commenter stated that the SEC should consider that ''the sheer number and complexity of the Proposals, when considered in their totality, if adopted, would impose staggering aggregate costs, as well as unprecedented operational and other practical challenges.'' [644] But, consistent with its long-standing practice, the Commission's economic analysis in each adopting release considers the incremental benefits and costs for the specific rule—that is, the benefits and costs stemming from that rule compared to the baseline.[645] In doing so, the Commission acknowledges that in some cases resource limitations can lead to higher compliance costs when the compliance period of the rule being considered overlaps with the compliance period of other rules. In determining compliance periods, the SEC considers the benefits of the rules as well as the costs of delayed compliance periods and potential overlapping compliance periods.

Specifically, some commenters, as noted above, mentioned the proposals which culminated in the recent adoptions of the May 2023 SEC Form PF Amending Release, SEC Private Funds Advisers Adopting Release, Beneficial Ownership Amending Release, Short Position Reporting Adopting Release, Securitizations Conflicts Adopting Release, Treasury Clearing Adopting Release, and Dealer Definition Amending Release.[646] The SEC

[629] *See supra* section II.A.3.

[630] *Id.*

[631] *See supra* section II.B.2. The incremental burdens associated with the use of these terms may be further limited because the recent amendments adopted by the SEC require a large hedge fund adviser to monitor and in certain instances report, the fund's RFACV in compliance with its current reporting obligation. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4.

[632] *Id.*

[633] *See supra* section II.C.2.a; *see also, e.g.,* SIFMA Comment Letter.

[634] *See supra* section II.C.2.a.

[635] *See supra* section II.C.2.b; *see also, e.g.,* MFA Comment Letter II; SIFMA Comment Letter; AIMA/ACC Comment Letter.

[636] *Id.*

[637] *See supra* section II.D; *see also* MFA Comment Letter II.

[638] *Id.*

[639] *See supra* footnotes 619 through 621 and accompanying text; *see also infra* section V.C.

[640] *See supra* section II.B.2.

[641] *Id.*

[642] *See, e.g.,* MFA Comment Letter; AIMA/ACC Comment Letter.

[643] *See supra* footnote 456 and accompanying text.

[644] MFA/NAPFM Comment Letter; *see also* MFA Comment Letter III; SIFMA Comment Letter; AIC Comment Letter I; AIC Comment Letter II; Comment Letter of U.S. House of Representatives Committee on Financial Services.

[645] *See supra* section IV.C.1.

[646] *See supra* section IV.C.1; *see also, e.g.,* AIC Comment Letter II; MFA Comment Letter I; MFA Comment Letter III; SIFMA Comment Letter.

acknowledges that there are compliance dates for certain requirements of these rules that overlap in time with the final rule, which may impose costs on resource constrained entities affected by multiple rules.[647] This may be particularly true for smaller entities with more limited compliance resources. This effect can negatively impact competition because these entities may be less able to absorb or pass on these additional costs, making it more difficult for them to remain in business or compete.

We do not think these increased costs from overlapping compliance periods will be significant for two reasons. First, the market participants that will be subject to the amendments in this rulemaking and who will be subject to one or more of the other recently adopted rules could be limited based on whether those participants' activities fall within the scope of the other rules.[648] Second, overlapping compliance burdens related specifically to implementation of recent Form PF amendments will be limited because of the scope and implementation periods of the May 2023 SEC Form PF Amending Release. Only the compliance period for amendments to section 4 of Form PF overlap with the compliance periods for the Form PF amendments in this rulemaking. As a result, smaller private fund advisers, who are the entities more likely to be resource constrained, will not face any heightened costs from overlapping implementation periods because only large private equity fund advisers—meaning those, together with their related persons that are not separately operated, with at least $2 billion in combined regulatory assets under management attributable to private equity funds—report on section 4.

Moreover, commenters' concerns about the costs of overlapping compliance periods were raised in the context of the proposal and, as discussed above, we have taken steps to reduce costs of the final rule in several ways from the proposal.[649] As a result, for both larger and smaller entities, any higher costs or potential negative effects on competition due to overlapping compliance periods raised in the context of the proposal may be mitigated under the final amendments.

Form PF collects confidential information about private funds and their trading strategies, and the inadvertent public disclosure of such competitively sensitive and proprietary information could adversely affect the funds and their investors. Some commenters expressed concerns at this possibility. For example, one commenter opposed the increased granularity in strategy categories, stating they could disclose a fund's proprietary investment information and present data security concerns.[650] However, the SEC anticipates that any risk of these adverse effects will be mitigated by certain aspects of the Form PF reporting requirements and controls and systems designed by the SEC for handling the data. For example, the SEC has controls and systems for the use and handling of the modified and new Form PF data in a manner that reflects the sensitivity of the data and is consistent with the maintenance of its confidentiality. The SEC has substantial experience with the storage and use of nonpublic information reported on Form PF as well as other nonpublic information that the SEC handles in the course of business.

D. Reasonable Alternatives

1. Alternatives to Amendments to General Instructions, Amendments To Enhance Data Quality, and Additional Amendments

The SEC considered alternatives to the amendments to general instructions, amendments to enhance data quality, and the additional amendments in the final rule (including the amendments to the process for requesting temporary hardship exemptions, by way of an amendment to 17 CFR 275.204(b)–1(f) under the Advisers Act). The alternatives considered were in the form of different choices of framing, level of additional detail requested by Form PF, level of detail removed from Form PF, and precise information targeted. For example, in the general instructions, the SEC considered an alternative that would have required advisers to report only at the master fund level or only at the feeder fund level. As another example, the SEC considered requiring annual filers to file within 30 calendar days after the end of their fiscal year, rather than 120 calendar days.

While many alternatives may have been able to capture more detailed information, or may have been able to capture relevant information with a smaller reporting burden for advisers, the SEC believes that each of the amendments to general instructions, amendments to enhance data quality, and additional amendments as adopted will improve data quality and enhance the usefulness of reported data without imposing undue reporting burden.

2. Alternatives to Amendments to Basic Information About the Adviser and the Private Funds It Advises

The SEC also considered alternatives to the amendments to basic information about advisers and the private funds they advise. As above, these alternatives were in the form of different choices of framing, level of additional detail requested by Form PF, level of detail removed from Form PF, and precise information targeted.

For example, with respect to identifying information for private funds in section 1a, the SEC considered an alternative that would provide more granularity for advisers to list categories of funds, such as differentiating between different types of funds of funds (for example, differentiating between multi-manager funds of funds and multi-asset funds of funds). As another example, with respect to basic information reported for all private funds in section 1b, the SEC considered alternatives that would limit reporting information about withdrawal rights, redemption rights, and contributions to only funds and advisers of a certain size.

As a final example, with respect to basic information reported for all hedge funds, the amendments will require advisers to identify each creditor or other counterparty (including CCPs) to which the reporting fund owes cash and synthetic financing borrowing (before posted collateral) equal to or greater than either (1) five percent of net asset value of the reporting fund as of the data reporting date or (2) $1 billion, but the SEC considered alternatives that would have changed the thresholds, either increasing or decreasing Form PF's definition of what constitutes a significant counterparty. With respect to several such questions, commenters

[647] The effective/compliance date of the amendments in this rulemaking is one year from the date of publication of the rules, which is anticipated to be in early 2025. *See infra* section II.F. *See supra* footnotes 461 through 467 (summarizing compliance dates for the previously adopted rules).

[648] The Short Position Reporting Adopting Release will require only institutional investment managers that meet or exceed certain reporting thresholds to report short position and short activity data for equity securities. The Securitizations Conflicts Adopting Release will affect only certain entities—and their affiliates and subsidiaries—that participate in securitization transactions. The Treasury Clearing Adopting Release will affect only those Form PF filers that participate in the secondary market for U.S. Treasury securities. Lastly, the Dealer Definition Amending Release will primarily affect certain principal trading firms and private funds; private funds will bear the compliance costs associated with registering as a broker-dealer—and those funds' advisers will have to complete the compliance activities for their funds—only if the funds' investment activities bring them within the scope of the amended definitions. *See supra* footnotes 464 through 467.

[649] See *supra* footnote 625 and accompanying text.

[650] SIFMA Comment Letter.

suggested the SEC consider alternative thresholds for reporting.[651] As discussed above, this threshold is appropriate because both portions of the threshold highlight potential systemic risk: five percent of net asset value is a level that represents significant exposure (based on the impact on performance) in the event of counterparty default, and $1 billion, while it may not equal five percent of a large hedge fund's assets, may indicate a larger systemic stress involving a fund's counterparties.[652]

The SEC believes that each of the amendments as adopted improve data quality and enhance the usefulness of reported data without imposing an undue reporting burden.

3. Alternatives to Amendments to Information About Hedge Funds Advised by Large Private Fund Advisers

The SEC considered alternatives to the amendments to information about hedge funds advised by large private fund advisers. As above, these alternatives were in the form of different choices of framing, level of additional detail requested by Form PF, level of detail removed from Form PF, and precise information targeted.

For example, with respect to investment exposure reporting, the final amendments will continue to require reporting on qualifying hedge fund exposures to different types of assets, but will revise the instructions and format of this reporting. As an alternative, the SEC considered an amendment that would require or permit large hedge fund advisers to file portfolio position-level information for qualifying hedge funds similar to what is required for large liquidity fund advisers, and large hedge fund advisers who do so would be allowed to forgo responding to certain specific investment exposure questions in section 2, including Question 30. The questions as adopted will improve data quality and enhance the usefulness of reported data without imposing an undue reporting burden.[653]

As another example, the SEC considered alternative approaches for instructing reporting advisers on how to net long and short positions for each sub-asset class. One prong of the amended instructions for netting long and short positions relies on a newly defined term ''reference asset,'' which we define as a security or other investment asset to which the reporting fund is exposed through direct ownership, synthetically, or indirect ownership,[654] and instructs advisers to net positions that have the same underlying reference asset across instrument types. The SEC considered instead tailoring these instructions to different asset classes. For example, the SEC considered instructing advisers to net repo exposures in accordance with generally accepted accounting principles (''GAAP'') rules for balance sheet netting, or instructing advisers with exposures whose underlying reference assets are Treasury securities to net within predefined maturity buckets. However, the SEC believes that providing netting instructions through the single definition of ''reference asset'' improves data quality and enhances the usefulness of report data without imposing undue burden.[655]

Commenters also suggested alternatives to questions requiring reporting of categories of large exposures, in particular suggesting alternative parameters or thresholds defining when exposures should be reported.[656] For example, for the proposed new questions requiring advisers to provide information for counterparties to which the reporting fund has net mark-to-market counterparty credit exposure which is equal to or greater than either (1) five percent of the reporting fund's net asset value as of the data reporting date or (2) $1 billion, after taking into account collateral received or posted by the reporting fund, one commenter suggested a threshold of 10 percent for this question.[657]

For each of these questions, the thresholds were chosen to highlight potentially significant systemic risks in keeping with industry practice. For example, for the above counterparty credit exposure question, five percent was identified as a level large enough to constitute a shock to a reporting fund's net asset value, and $1 billion was identified as an amount that in the case of a very large counterparty, may not represent five percent of its net assets, but may be large enough to create stress for the reporting fund.[658] As another example, for the question on country and industry exposures, the threshold of either (1) five percent of net asset value or (2) $1 billion is appropriate for multiple reasons, such as the fact that it represents a material level of portfolio exposure to risk relating to individual countries and geographic regions, and the fact that, for funds without a benchmark, five percent is often evaluated for industry, individual position, and country risk, and is a common and easy-to-measure threshold.[659] With respect to the $1 billion threshold, it constitutes sufficiently large nominal value exposure from a risk perspective.[660]

As a final example, the SEC also considered requiring advisers to report Dollar Value of one basis point (DV01) instead of the 10-year zero coupon bond equivalent. We understand that the 10-year zero coupon bond equivalent is the most widely used duration measure currently applied in the industry, and would require the fewest number of private funds to update their calculations of duration to comply with the reporting requirement.[661]

Broadly, the SEC believes that each of the amendments as adopted improve data quality and enhance the usefulness of reported data without imposing undue reporting burden.[662]

4. Alternatives to the Definition of the Term ''Hedge Fund''

The SEC also considered amending the definition of ''hedge fund'' which is defined in the Glossary of Terms as any private fund (other than a securitized asset fund) (a) with respect to which one or more investment advisers (or related persons of investment advisers) may be paid a performance fee or allocation calculated by taking into account unrealized gains (other than a fee or allocation the calculation of which may take into account unrealized gains solely for the purpose of reducing such fee or allocation to reflect net unrealized losses); (b) that may borrow an amount in excess of one-half of its net asset value (including any committed capital) or may have gross notional exposure in excess of twice its net asset value (including any committed capital); or (c) that may sell securities or other assets short or enter into similar transactions (other than for the purpose of hedging currency exposure or managing duration).[663]

Under the existing definition, an adviser to a fund that holds itself out as a private equity fund and is permitted in its fund governing documents to engage in certain short-selling, but has not done so in the past 12 months, would be reported in Form PF data as

[651] *See supra* sections II.B.3, II.C.2.

[652] *Id.*

[653] *See supra* section II.C.

[654] *See* Form PF Glossary of Terms. The amendments will also instruct advisers to net fixed income positions that fall within certain predefined maturity buckets. *See supra* section II.C.

[655] *See supra* section II.C.

[656] *See supra* sections II.B.3, II.C.2.

[657] MFA Comment Letter II.

[658] *See supra* section II.B.3.

[659] *See supra* section II.C.2.d.

[660] *Id.*

[661] *See supra* section II.C.2.d.

[662] *See supra* section II.C.2.d.

[663] *Id.*

a hedge fund with zero short exposure. The SEC therefore considered a potential alternative definition of ''hedge fund,'' under which, to qualify as a hedge fund under the leverage prong of the potential alternative definition, a fund would have to satisfy subsection (b) of the definition (the leverage prong), as it does today, but also must have actually borrowed or used any leverage during the past 12 months, excluding any borrowings secured by unfunded commitments (*i.e.,* subscription lines of credit). Additionally, to qualify as a hedge fund under the short selling prong of the potential alternative definition (the short selling prong), the fund would have engaged in certain short selling during the past 12 months. The SEC also considered alternative definitions requiring, for example, longer or shorter time periods, different time periods for borrowing versus short selling, or requirements for the reporting fund to provide redemption rights in the ordinary course.

An alternative definition could reduce the unnecessary reporting burden faced by advisers to deemed hedge funds that hold themselves out as private equity funds but currently comply with instructions to report information on Form PF section 2; however, this benefit would be partially mitigated by the impacted private fund advisers who would then need to report on necessary Form PF sections for private equity fund advisers.[664] Some reporting funds may consider themselves ''private equity funds,'' but advisers report them as hedge funds, because the reporting fund's governing documents permit the fund to engage in certain borrowing and short selling (even though it did not do so at any time in the past 12 months), and an alternative definition could result in these funds reporting in a manner more consistent with their own view of their fund strategy. As discussed above, certain commenters supported revising the definition, including offering alternative specific definitions.[665]

However, the current definition of ''hedge fund'' is designed to include any private fund having any one of three common characteristics of a hedge fund: (1) a performance fee, (2) leverage, or (3) short selling. Any private fund that has one or more of these characteristics is an appropriate subject for the more detailed level of reporting that hedge funds are subject to on Form PF because the questions that hedge fund advisers are required to complete focus on these activities, and these activities may contribute to systemic risk, particularly in the case of a fund that has the ability to engage in borrowing or short selling.

A revised definition that focuses on actual or contemplated use could therefore have resulted in incomplete data for funds engaged in these activities, meaning incomplete data on activities that are important potential contributors to systemic risk. Because short selling and borrowing are important distinguishing characteristics of hedge funds and providing any exception for these activities, including a *de minimis* one, could have a significant, negative effect on reporting.[666]

Moreover, because a reporting fund may vary from year to year in its use of leverage or short selling, a revised definition that focuses on actual or contemplated use would also have caused fluctuations in the data from year to year, depending on which funds use leverage or short selling in a particular year, potentially impacting the quality or usefulness of resulting data. In particular, when first adopting the current definition, the Commissions reasoned that even a reporting fund for which leverage or short selling is an important part of its strategy may not engage in that practice during every reporting period.[667] This effect could also have increased the burden on advisers to the extent that their funds were required to fluctuate between different reporting categories in different reporting periods, depending on the fund's practices in any given period.[668] The potential costs of this alternative definition would also have included transition filing costs for advisers impacted by the definition, who would have been required to update their reporting methods to capture information from their funds relevant for reporting on Form PF as a private equity fund instead of as a hedge fund, and completing corresponding sections of the form targeted at each category.[669]

V. Paperwork Reduction Act

CFTC:

The information collection titled ''Form PF and Rule 204(b)–1'' (OMB Control No. 3235–0679) was issued to the SEC and implements sections 404 and 406 of the Dodd-Frank Act by requiring private fund advisers that have at least $150 million in private fund assets under management to report certain information regarding the private funds they advise on Form PF. The SEC makes information on Form PF available to the CFTC, subject to the confidentiality provisions of the Dodd-Frank Act, and the CFTC may use information collected on Form PF in its regulatory programs, including examinations, investigations and investor protection efforts relating to private fund advisers.

CFTC rule 4.27[670] does not impose any additional burden upon registered CPOs and CTAs that are dually registered as investment advisers with the SEC (''dual registrants''). There is no requirement to file Form PF with the CFTC, and any filings made by dual registrants with the SEC are made pursuant to the Advisers Act. While CFTC rule 4.27(d) states that dually registered CPOs and CTAs that file Form PF with the SEC will be deemed to have filed Form PF with the CFTC for purposes of any enforcement action regarding any false or misleading statement of material fact in Form PF, the CFTC is not imposing any additional burdens herein. Therefore, any burden imposed by Form PF on entities registered with both the CFTC and the SEC has been fully accounted for within the SEC's calculations regarding the impact of this collection of information under the Paperwork Reduction Act of 1995 (''PRA''), as set forth below.[671]

SEC:

Certain provisions of the final Form PF and rule 204(b)–1 revise an existing ''collection of information'' within the meaning of the PRA.[672] The SEC published a notice requesting comment on changes to this collection of information in the 2022 Joint Form PF Proposing Release and submitted the collection of information to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[673] The title for the collection of information we are amending is ''Form PF and Rule 204(b)–1'' (OMB Control Number 3235–0679), and includes both Form PF and rule 204(b)–1 (''the rules'').[674] The SEC's solicitation of

[664] *See supra* sections II.C.2; IV.C.2; *see also infra* section V.C.

[665] *See supra* section II.C.2.d.

[666] *Id.*

[667] *See supra* footnote 3; *see also* 2011 Form PF Adopting Release, at text accompanying footnote 4.

[668] *See supra* section II.C.2.d.

[669] We estimate that the average cost of a transition filing is $20.50. *See* Table 9.

[670] CFTC rule 4.27, 17 CFR 4.27, was adopted pursuant to the CFTC's authority set forth in section 4n of the Commodity Exchange Act, 7 U.S.C. 6n. CFTC regulations are found at Title 17 Chapter I of the Code of Federal Regulations.

[671] 44 U.S.C. 3501 through 3521.

[672] *Id.*

[673] 44 U.S.C. 3507(d); 5 CFR 1320.11.

[674] The SEC also submitted the collection of information to OMB on Sept. 29, 2023, in connection with the May 2023 SEC Form PF Amending Release (ICR Reference No. 202305–3235–023), which OMB approved on Dec. 18, 2023,

Continued

public comments included estimating and requesting public comments on the burden estimates for all information collections under this OMB control number (*i.e.,* both changes associated with the rulemaking and other burden updates). These changes in burden also reflect the SEC's revision and update of burden estimates since the proposal for all information collections under this OMB control number (whether or not associated with rulemaking changes) and responses to the SEC's request for public comment on all information collection burden estimates for this OMB control number. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Compliance with the information collection titled ''Form PF and Rule 204(b)–1'' is mandatory. The respondents are investment advisers that (1) are registered or required to be registered under Advisers Act section 203, (2) advise one or more private funds, and (3) managed private fund assets of at least $150 million at the end of their most recently completed fiscal year (collectively, with their related persons).[675] Form PF divides respondents into groups based on their size and types of private funds they manage, requiring some groups to file more information more frequently than others. The types of respondents are (1) smaller private fund advisers, that report annually (*i.e.,* private fund advisers that do not qualify as large private fund advisers), (2) large hedge fund advisers, that report more information quarterly (*i.e.,* advisers with at least $1.5 billion in hedge fund assets under management), (3) large liquidity fund advisers, that report more information quarterly (*i.e.,* advisers that manage liquidity funds and have at least $1 billion in combined money market and liquidity fund assets under management), and (4) large private equity fund advisers, that report more information annually (*i.e.,* advisers with at least $2 billion in private equity fund assets under management).[676] As discussed more fully in section II above and as summarized in sections V.A and V.C below, the amendments revise how all types of respondents report certain information on Form PF.

We have revised our burden estimates in response to comments we received, to reflect modifications from the proposal, to incorporate the Form PF amendments that were separately adopted since the proposal,[677] and to take into consideration updated data. One commenter indicated that the proposed amendments would confer more benefits than costs.[678] We received other comments to our time and cost burdens indicating that we underestimated the burdens to implement the proposed amendments to Form PF.[679] We also received comments on aspects of the economic analysis that implicated estimates we used to calculate the collection of information burdens.[680] We discuss these comments below.

We were persuaded by commenters who asserted that the proposed burdens underestimated the time and expense associated with the proposed amendments. Upon further consideration, we believe that it will take more time than initially contemplated in the proposal to collect the applicable data and report on Form PF. To address commenters' concerns and recognizing the changes from the proposal discussed above in section II, we are revising the estimates as reflected in the charts below.

As discussed more fully in section II above, we have also modified certain proposed requirements in a manner that changes our burden estimates in certain respects. For example, as discussed more fully in section II.A.2 above, we are adopting amendments to require consolidated reporting of trading vehicles, rather than separate reporting, as proposed, which reduces our burden estimates. One commenter stated that the proposed amendments to require disaggregated reporting of trading vehicles would require building of new reporting systems and that the Commissions' estimated costs were understated, particularly for private equity fund advisers.[681] Some commenters stated that certain proposed amendments requiring more granular reporting would impose significant costs and burdens on advisers, such as the proposed requirements for look-through reporting, exposures, performance, and market factor reporting.[682] As discussed more fully in section II.C above, we have modified the proposed requirements for large hedge fund advisers to report certain fund exposures to allow advisers to report the exposure category that best represents the reporting fund's exposure, which will reduce the burden on advisers in collecting and reporting this information.[683] We have also adopted a modification from the proposal which permits an adviser to report a fund's monthly asset value as a GRFACV or an RFACV, rather than gross asset value or net asset value, in the event that these values are not calculated on a monthly basis, which is a less burdensome metric to calculate.[684] Further, we are not adopting a proposed question on portfolio correlation, as discussed more fully in section II.C.2 above, after consideration of comments that stated the question would impose significant burdens on advisers because the calculation would be complex to perform and is not risk measurement that advisers currently calculate.[685]

Some commenters stated that the proposed cost estimates were understated because they do not take into consideration the costs of the amendments proposed in the 2022 SEC Form PF Proposing Release.[686] Our final estimates have been revised to include the effect of the Form PF amendments that were adopted subsequent to the 2022 Joint Form PF Proposal.[687] Our time and cost estimates also incorporate other adjustments, which are not based on changes from the proposed amendments, for updated data for the estimated number of respondents and

available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202305-3235-023. See May 2023 SEC Form PF Amending Release, *supra* footnote 4. Following this, the SEC submitted the collection of information to OMB on Jan. 11, 2024, in connection with the July 2023 Form PF Amending Release (ICR Reference No. 202401–3235–005), which is currently pending, *available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202401-3235-005. See* July 2023 SEC Form PF Amending Release, *supra* footnote 4. The previously approved estimates used in this PRA do not reflect this submission to OMB in connection with the July 2023 Form PF Amending Release.

[675] *See* 17 CFR 275.204(b)–1.

[676] Large hedge fund advisers to qualifying hedge funds also file current reports as soon as practicable, but no later than 72 hours from the occurrence of certain reporting events, as provided for in Form PF section 5. Private equity fund advisers also file private equity event reports within 60 days from fiscal quarter end upon the occurrence of certain reporting reports, as provided for in Form PF section 6. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4.

[677] *See* May 2023 SEC Form PF Amending Release and July 2023 SEC Form PF Amending Release, *supra* footnote 4.

[678] Better Markets Comment Letter.

[679] *See, e.g.,* AIC Comment Letter I; MFA Comment Letter II; MFA/NAPFM Comment Letter; SIFMA Comment Letter.

[680] *See, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II; SIFMA Comment Letter.

[681] AIC Comment Letter I.

[682] *See, e.g.,* AIMA/ACC Comment Letter; USCC Comment Letter.

[683] *See, e.g.,* Questions 32, 33, 35, and 36.

[684] *See* Questions 11 and 12.

[685] Proposed Question 48; s*ee, e.g.,* AIMA/ACC Comment Letter; MFA Comment Letter II.

[686] *See, e.g.,* AIC Comment Letter I; AIC Comment Letter II; MFA Comment Letter III; SIFMA Comment Letter; *see also* 2022 SEC Form PF Proposing Release, *supra* footnote 4.

[687] *See* May 2023 SEC Form PF Amending Release and July 2023 SEC Form PF Amending Release, *supra* footnote 4.

salary/wage information across all filer types.

A. Purpose and Use of the Information Collection

The rules implement provisions of Title IV of the Dodd-Frank Act, which amended the Advisers Act to require the SEC to, among other things, establish reporting requirements for advisers to private funds.[688] The information collected on Form PF is designed to facilitate FSOC's obligations under the Dodd-Frank Act to monitor of systemic risk in the private fund industry.[689] The SEC also may use information collected on Form PF in its regulatory programs, including examinations, investigations, and investor protection efforts relating to private fund advisers.[690]

The final amendments are designed to enhance FSOC's ability to monitor systemic risk as well as bolster the SEC's regulatory oversight of private fund advisers and investor protection efforts. The final amendments amend the form's general instructions, as well as section 1 of Form PF, which apply to all Form PF filers. The final amendments also amend section 2 of Form PF, which applies to large hedge fund advisers that advise qualifying hedge funds (*i.e.,* hedge funds with a net asset value of at least $500 million).

B. Confidentiality

Responses to the information collection will be kept confidential to the extent permitted by law.[691] Form PF elicits non-public information about private funds and their trading strategies, the public disclosure of which could adversely affect the funds and their investors. The SEC does not intend to make public Form PF information that is identifiable to any particular adviser or private fund, although the SEC may use Form PF information in an enforcement action and FSOC may use it to assess potential systemic risk.[692] SEC staff issues certain publications designed to inform the public of the private funds industry, all of which use only aggregated or masked information to avoid potentially disclosing any proprietary information.[693] The Advisers Act precludes the SEC from being compelled to reveal Form PF information except (1) to Congress, upon an agreement of confidentiality, (2) to comply with a request for information from any other Federal department or agency or self-regulatory organization for purposes within the scope of its jurisdiction, or (3) to comply with an order of a court of the United States in an action brought by the United States or the SEC.[694] Any department, agency, or self-regulatory organization that receives Form PF information must maintain its confidentiality consistent with the level of confidentiality established for the SEC.[695] The Advisers Act requires the SEC to make Form PF information available to FSOC.[696] For advisers that are also commodity pool operators or commodity trading advisers, filing Form PF through the Form PF filing system is filing with both the SEC and CFTC.[697] Therefore, the SEC makes Form PF information available to FSOC and the CFTC, pursuant to Advisers Act section 204(b), making the information subject to the confidentiality protections applicable to information required to be filed under that section. Before sharing any Form PF information, the SEC requires that any such department, agency, or self-regulatory organization represent to the SEC that it has in place controls designed to ensure the use and handling of Form PF information in a manner consistent with the protections required by the Advisers Act. The SEC has instituted procedures to protect the confidentiality of Form PF information in a manner consistent with the protections required in the Advisers Act.[698]

C. Burden Estimates

We are revising our total burden final estimates to reflect the final amendments, updated data, new methodology for certain estimates, subsequent Form PF amendments adopted after the 2022 Joint Form PF Proposing Release, and comments we received to our estimates.[699] The tables below map out the proposed and final Form PF requirements as they apply to each group of respondents and detail our burden estimates.

a. Proposed Form PF Requirements by Respondent

TABLE 1a—PROPOSED FORM PF REQUIREMENTS BY RESPONDENT

Form PF	Smaller private fund advisers	Large hedge fund advisers	Large liquidity fund advisers	Large private equity fund advisers
Section 1a and section 1b (basic information about the adviser and the private funds it advises). *Proposed revisions*.	Annually	Quarterly	Quarterly	Annually.
Section 1c (additional information concerning hedge funds). *Proposed revisions*.	Annually, if they advise hedge funds.	Quarterly	Quarterly, if they advise hedge funds.	Annually, if they advise hedge funds.
Section 2 (additional information concerning qualifying hedge funds). *Proposed revisions*.	No	Quarterly	No	No.

[688] *See* 15 U.S.C. 80b–4(b) and 15 U.S.C. 80b–11(e).

[689] *See* Form PF.

[690] *Id.*

[691] *See* 5 CFR 1320.5(d)(2)(vii) and (viii).

[692] *See* 15 U.S.C. 80b–10(c) and 15 U.S.C. 80b–4(b).

[693] S*ee, e.g.,* Private Funds Statistics, issued by staff of the SEC Division of Investment Management's Analytics Office, which we have used in this PRA as a data source, *available at https://www.sec.gov/divisions/investment/private-funds-statistics.shtml.*

[694] *See* 15 U.S.C. 80b–4(b)(8).

[695] *See* 15 U.S.C. 80b–4(b)(9).

[696] *See* 15 U.S.C. 80b–4(b)(7).

[697] *See* 2011 Form PF Adopting Release, *supra* footnote 4, at n.17.

[698] *See* 5 CFR 1320.5(d)(2)(viii).

[699] For the previously approved estimates, *see* ICR Reference No. 202305–3235–023 (conclusion date Dec. 18, 2023), *available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202305-3235-023*. The 2022 Joint Form PF Proposing Release used the then-current previously approved estimates, *see* ICR Reference No. 202011–3235–019 (conclusion date Apr. 1, 2021), *available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202011-3235-019.*

TABLE 1a—PROPOSED FORM PF REQUIREMENTS BY RESPONDENT—Continued

Form PF	Smaller private fund advisers	Large hedge fund advisers	Large liquidity fund advisers	Large private equity fund advisers
Section 3 (additional information concerning liquidity funds). *No proposed revisions*.	No	No	Quarterly	No.
Section 4 (additional information concerning private equity funds).*No proposed revisions*.	No	No	No	Annually.
Section 5 (temporary hardship request). *The proposal would revise filing instructions*.	Optional, if they qualify	Optional, if they qualify	Optional, if they qualify	Optional, if they qualify.
Transition Filings (indicating the adviser is no longer obligated to file on a quarterly basis). *No proposed revisions*.	Not applicable	If they cease to qualify as a large hedge fund adviser.	If they cease to qualify as a large liquidity fund adviser.	Not applicable.
Final Filings (indicating the adviser is no longer subject to the rules). *No proposed revisions*.	If they qualify	If they qualify	If they qualify	If they qualify.

b. Adopted Form PF Requirements by Respondent

ADOPTED FORM PF REQUIREMENTS BY RESPONDENT

Form PF	Smaller private fund advisers	Large hedge fund advisers	Large liquidity fund advisers	Large private equity fund advisers
Section 1a and section 1b (basic information about the adviser and the private funds it advises). *The final rules modify section 1a and section 1b*.	Annually	Quarterly	Quarterly	Annually.
Section 1c (additional information concerning hedge funds). *The final rules modify section 1c*.	Annually, if they advise hedge funds.	Quarterly	Quarterly, if they advise hedge funds.	Annually, if they advise hedge funds.
Section 2 (additional information concerning qualifying hedge funds). *The final rules modify section 2*.	No	Quarterly	No	No.
Section 3 (additional information concerning liquidity funds). *No final revisions*.	No	No	Quarterly	No.
Section 4 (additional information concerning private equity funds). *No final revisions*.	No	No	No	Annually.
Section 5 (current reporting concerning qualifying hedge funds). [1] *No final revisions*.	No	As soon as practicable upon a current reporting event, but no later than 72 hours.	No	No.
Section 6 (event reporting for private equity fund advisers).[1] *No final revisions*.	Within 60 days of fiscal quarter end upon a reporting event, if they advise private equity funds.	No	No	Within 60 days of fiscal quarter end upon a reporting event.
Section 7 (temporary hardship request)[1] *The final rules revise the filing instructions*.	Optional, if they qualify	Optional, if they qualify	Optional, if they qualify	Optional, if they qualify.

ADOPTED FORM PF REQUIREMENTS BY RESPONDENT—Continued

Form PF	Smaller private fund advisers	Large hedge fund advisers	Large liquidity fund advisers	Large private equity fund advisers
Transition Filings (indicating the adviser is no longer obligated to file on a quarterly basis). No final revisions.	Not applicable	If they cease to qualify as a large hedge fund adviser.	If they cease to qualify as a large liquidity fund adviser.	Not applicable.
Final Filings (indicating the adviser is no longer subject to the rules). *No final revisions.*	If they qualify	If they qualify	If they qualify	If they qualify.

Note:
[1] The SEC adopted amendments to Form PF, which added sections 5 and 6 and redesignated the previous section 5 as section 7. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4.

c. Annual Hour Burden Estimates

Below are tables with annual hour burden estimates for (1) initial filings, (2) ongoing annual and quarterly filings, (3) current reporting and private equity event reporting, and (4) transition filings, final filings, and temporary hardship requests.

TABLE 2—ANNUAL HOUR BURDEN ESTIMATES FOR INITIAL FILINGS

Respondent [1]	Number of respondents = aggregate number of responses [2]	Hours per response [3]		Hours per response amortized over 3 years [4]	Aggregate hours amortized over 3 years [5]
Smaller Private Fund Advisers:					
Proposed Estimate	[6] 309	50	÷ 3 =	17	5,253
Final Estimate	[7] 374	55	÷ 3 =	18	6,732
Previously Approved	358	40	÷ 3 =	13	4,654
Change	16	15		5	2,078
Large Hedge Fund Advisers:					
Proposed Estimate	[8] 15	345	÷ 3 =	115	1,725
Final Estimate	[9] 14	380	÷ 3 =	127	1,778
Previously Approved	16	325	÷3 =	108	1,728
Change	(2)	55		19	50
Large Liquidity Fund Advisers:					
Proposed Estimate	[10] 1	210	÷ 3 =	70	70
Final Estimate	[11] 1	229	÷ 3 =	76	76
Previously Approved	1	200	÷ 3 =	67	67
Change	0	29		9	9
Large Private Equity Fund Advisers:					
Proposed Estimate	[12] 13	210	÷ 3 =	70	910
Final Estimate	[13] 18	281	÷ 3 =	94	1,692
Previously Approved	17	252	÷ 3 =	84	1,428
Change	1	29		10	264

Notes:
[1] We expect that the hourly burden will be most significant for the initial report because the adviser will need to familiarize itself with the new reporting form and may need to configure its systems in order to efficiently gather the required information. In addition, we expect that some large private fund advisers will find it efficient to automate some portion of the reporting process, which will increase the burden of the initial filing but reduce the burden of subsequent filings.
[2] This concerns the initial filing; therefore, we estimate one response per respondent. The proposed and final changes are due to using updated data to estimate the number of advisers.
[3] Hours per response changes are due to the amendments, as well as amendments to Form PF adopted subsequent to the 2022 Joint Form PF Proposal for the final estimates and comments we received to our estimates.
[4] We amortize the initial time burden over three years because we believe that most of the burden will be incurred in the initial filing.
[5] (Number of responses) × (hours per response amortized over three years) = aggregate hours amortized over three years. Changes are due to (1) using updated data to estimate the number of advisers, (2) the amendments adopted in this Release, (3) amendments to Form PF adopted subsequent to the 2022 Joint Form PF Proposal, and (4) comments we received to our estimates.
[6] In the case of the proposed estimates, Private Funds Statistics show 2,394 smaller private fund advisers filed Form PF in the third quarter of 2021. Based on filing data from the last five years, an average of 12.9% of them did not file for the previous due date. (2,394 × 0.129 = 309 advisers.)
[7] In the case of the final estimates, Private Funds Statistics show 2,750 smaller private fund advisers filed Form PF in the first quarter of 2023. Based on filing data from the last five years, an average of 13.6% of them did not file for the previous due date. (2,750 × 0.136 = 374 advisers.)
[8] In the case of the proposed estimates, Private Funds Statistics show 592 large hedge fund advisers filed Form PF in the third quarter of 2021. Based on filing data from the last five years, an average of 2.6% of them did not file for the previous due date. (592 × 0.026 = 15 advisers.)

[9] In the case of the final estimates, Private Funds Statistics show 570 large hedge fund advisers filed Form PF in the first quarter of 2023. Based on filing data from the last five years, an average of 2.5% of them did not file for the previous due date. (570 × 0.025 = 14 advisers.)

[10] In the case of the proposed estimates, Private Funds Statistics show 24 large liquidity fund advisers filed Form PF in the third quarter of 2021. Based on filing data from the last five years, an average of 1.5% of them did not file for the previous due date. (24 × 0.015 = 0.36 advisers, rounded up to 1 adviser.)

[11] In the case of the final estimates, Private Funds Statistics show 21 large liquidity fund advisers filed Form PF in the first quarter of 2023. Based on filing data from 2017 through 2021, an average of 1.5% of them did not file for the previous due date. (21 × 0.015 = 0.32 advisers, rounded up to 1 adviser.)

[12] In the case of the proposed estimates, Private Funds Statistics show 369 large private equity fund advisers filed Form PF in the third quarter of 2021. Based on filing data from the last five years, an average of 3.5% of them did not file for the previous due date. (369 × 0.035 = 13 advisers.)

[13] In the case of the final estimates, Private Funds Statistics show 450 large private equity fund advisers filed Form PF in the first quarter of 2023. Based on filing data from the last five years, an average of 3.9% of them did not file for the previous due date. (450 × 0.039 = 18 advisers.)

TABLE 3—ANNUAL HOUR BURDEN ESTIMATES FOR ONGOING ANNUAL AND QUARTERLY FILINGS

Respondent [1]	Number of respondents [2] (advisors)		Number of responses [3]		Hours per response [4]		Aggregate hours [5]
Smaller Private Fund:							
Proposed Estimate	[6] 2,085	×	1	×	20	=	41,700
Final Estimate	[7] 2,376	×	1	×	22	=	52,272
Previously Approved	2,258	×	1	×	15	=	33,870
Change	118		0		7		18,402
Large Hedge Fund:							
Proposed Estimate	[8] 577	×	4	×	160	=	369,280
Final Estimate	[9] 556	×	4	×	176	=	391,424
Previously Approved	582	×	4	×	150	=	349,200
Change	(26)		0		26		42,224
Large Liquidity Fund:							
Proposed Estimate	[10] 23	×	4	×	75	=	6,900
Final Estimate	[11] 20	×	4	×	86	=	6,880
Previously Approved	21	×	4	×	70	=	5,880
Change	(1)		0		16		1,000
Large Private Equity Fund:							
Proposed Estimate	[12] 356	×	1	×	105	=	37,380
Final Estimate	[13] 432	×	1	×	145	=	62,640
Previously Approved	418	×	1	×	128	=	53,504
Change	14		0		17		9,136

Notes:

[1] We estimate that after an adviser files its initial report, it will incur significantly lower costs to file ongoing annual and quarterly reports, because much of the work for the initial report is non-recurring and likely created system configuration and reporting efficiencies.

[2] Changes to the number of respondents are due to using updated data to estimate the number of advisers.

[3] Smaller private fund advisers and large private equity fund advisers file annually. Large hedge fund advisers and large liquidity fund advisers file quarterly.

[4] Hours per response changes are due to the amendments.

[5] Changes to the aggregated hours are due to (1) using updated data to estimate the number of advisers, (2) the amendments, (3) amendments to Form PF adopted subsequent to the 2022 Joint Form PF Proposing Release, and (4) comments we received to our estimates.

[6] In the case of the proposed estimates, Private Funds Statistics show 2,394 smaller private fund advisers filed Form PF in the third quarter of 2021. We estimated that 309 of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (2,394 total smaller advisers − 309 advisers that made an initial filing = 2,085 advisers that make ongoing filings.)

[7] In the case of the final estimates, Private Funds Statistics show 2,750 smaller private fund advisers filed Form PF in the first quarter of 2023. We estimated that 374 of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (2,750 total smaller advisers − 374 advisers that made an initial filing = 2,376 advisers that make ongoing filings.)

[8] In the case of the proposed estimates, Private Funds Statistics show 592 large hedge fund advisers filed Form PF in the third quarter of 2021. We estimated that 15 of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (592 total large hedge fund advisers − 15 advisers that made an initial filing = 577 advisers that make ongoing filings.)

[9] In the case of the final estimates, Private Funds Statistics show 570 large hedge fund advisers filed Form PF in the first quarter of 2023. We estimated that 14 of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (570 total large hedge fund advisers − 14 advisers that made an initial filing = 556 advisers that make ongoing filings.)

[10] In the case of the proposed estimates, Private Funds Statistics show 24 large liquidity fund advisers filed Form PF in the third quarter of 2021. We estimated that one of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (24 total large liquidity fund advisers − 1 adviser that made an initial filing = 23 advisers that make ongoing filings.)

[11] In the case of the final estimates, Private Funds Statistics show 21 large liquidity fund advisers filed Form PF in the first quarter of 2023. We estimated that one of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (21 total large liquidity fund advisers − 1 adviser that made an initial filing = 20 advisers that make ongoing filings.)

[12] In the case of the proposed estimates, Private Funds Statistics show 369 large private equity fund advisers filed Form PF in the third quarter of 2021. We estimated that 13 of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (369 total large private equity fund advisers − 13 advisers that made an initial filing = 356 advisers that make ongoing filings.)

[13] In the case of the final estimates, Private Funds Statistics show 450 large private equity fund advisers filed Form PF in the first quarter of 2023. We estimated that 18 of them filed an initial filing, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. (450 total large private equity fund advisers − 18 advisers that made an initial filing = 432 advisers that make ongoing filings.)

TABLE 4—ANNUAL HOUR BURDEN ESTIMATES FOR CURRENT REPORTING AND PRIVATE EQUITY EVENT REPORTING [1]

Respondent	Aggregate number of responses		Hours per response		Aggregate hours
Smaller Private Fund Advisers:					
Proposed Estimate	Not Applicable				
Final Estimate	20	×	5	=	100
Previously Approved	20	×	5	=	100
Change	0	×	0	=	0
Large Hedge Fund Advisers:					
Proposed Estimate	Not Applicable				
Final Estimate	60	×	10	=	600
Previously Approved	60	×	10	=	600
Change	0	×	0	=	0
Large Private Equity Fund Advisers:					
Proposed Estimate	Not Applicable				
Final Estimate	20	×	5	=	100
Previously Approved	20	×	5	=	100
Change	0	×	0	=	0

Note:
[1] Subsequent to the 2022 Joint Form PF Proposing Release, the SEC adopted amendments to Form PF, which added Form PF section 5 (Current report for large hedge fund advisers to qualifying hedge funds) and section 6 (Quarterly report for advisers to private equity funds) to Form PF. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4, at section V for proposed and final estimates for current reporting and private equity event reporting. We did not propose any changes to these sections in the 2022 Joint Form PF Proposing Release and are not adopting any changes to these sections in this Release.

TABLE 5—ANNUAL HOUR BURDEN ESTIMATES FOR TRANSITION FILINGS, FINAL FILINGS, AND TEMPORARY HARDSHIP REQUESTS

Filing type [1]	Aggregate number of responses [2]		Hours per response		Aggregate hours [3]
Transition Filing from Quarterly to Annual:					
Proposed Estimate	[4] 68	×	0.25	=	17
Final Estimate	[5] 69	×	0.25	=	17.25
Previously Approved	71	×	0.25	=	17.75
Change	(2)		0		(0.50)
Final Filings:					
Proposed Estimate	[6] 233	×	0.25	=	58.25
Final Estimate	[7] 243	×	0.25	=	60.75
Previously Approved	235	×	0.25	=	58.75
Change	8		0		2
Temporary Hardship Requests:					
Proposed Estimate	[8] 3	×	1	=	3
Final Estimate	[9] 4	×	1	=	4
Previously Approved	4	×	1	=	4
Change	0		0		0

Notes:
[1] Advisers make limited Form PF filings in three situations. First, any adviser that transitions from filing quarterly to annually because it has ceased to qualify as a large hedge fund adviser or large liquidity fund adviser, must file a Form PF indicating that it is no longer obligated to report on a quarterly basis. Second, any adviser that is no longer subject to Form PF's reporting requirements, must file a final filing indicating this. Third, an adviser may request a temporary hardship exemption if it encounters unanticipated technical difficulties that prevent it from making a timely electronic filing. A temporary hardship exemption extends the deadline for an electronic filing for seven business days. To request a temporary hardship exemption, the adviser must file a request on Form PF. The final rule amends how advisers file temporary hardship exemption requests, as discussed in section II.E of this Release; however, the amendment will not result in any changes to the hours per response.
[2] Changes to the aggregate number of responses are due to using updated data.
[3] Changes to the aggregate hours are due to the changes in the aggregate number of responses.
[4] In the case of the proposed estimates, Private Funds Statistics show 616 advisers filed quarterly reports in the third quarter of 2021. Based on filing data from the last five years, an average of 11.1% of them filed a transition filing. (616 × 0.111 = 68 responses.)
[5] In the case of the final estimates, Private Funds Statistics show 591 advisers filed quarterly reports in the first quarter of 2023. Based on filing data from the last five years, an average of 11.7% of them filed a transition filing. (591 × 0.117 = 69 responses.)
[6] In the case of the proposed estimates, Private Funds Statistics show 3,379 advisers filed Form PF in the third quarter of 2021. Based on filing data from the last five years, an average of 6.9% of them filed a final filing. (3,379 × 0.069 = approximately 233 responses.)
[7] In the case of the final estimates, Private Funds Statistics show 3,791 advisers filed Form PF in the first quarter of 2023. Based on filing data from the last five years, an average of 6.4% of them filed a final filing. (3,791 × 0.064 = approximately 243 responses.)
[8] In the case of the proposed estimates, based on experience receiving temporary hardship requests, we estimate that 1 out of 1,000 advisers will file a temporary hardship exemption annually. Private Funds Statistics show 3,379 advisers filed Form PF in the third quarter of 2021. (3,379/1,000 = approximately 3 responses.)

[9] In the case of the final estimates, based on experience receiving temporary hardship requests, we estimate that 1 out of 1,000 advisers will file a temporary hardship exemption annually. Private Funds Statistics show 3,791 advisers filed Form PF in the first quarter of 2023. (3,791/1,000 = approximately 4 responses.)

d. Annual Monetized Time Burden Estimates

Below are tables with annual monetized time burden proposed and final estimates for (1) initial filings, (2) ongoing annual and quarterly filings, (3) current reporting and private equity event reporting, and (4) transition filings, final filings, and temporary hardship requests.[700]

TABLE 6—ANNUAL MONETIZED TIME BURDEN OF INITIAL FILINGS

Respondent [1]	Per response [2]		Per response amortized over 3 years [3]		Aggregate number of responses [4]		Aggregate monetized time burden amortized over 3 years
Smaller Private Fund Advisers:							
Proposed Estimate	[5] $18,250	÷ 3 =	$6,083	×	309	=	$1,879,647
Final Estimate	[6] 21,340	÷ 3 =	7,113	×	374	=	2,660,262
Previously Approved	15,520	÷ 3 =	5,174	×	358	=	1,852,292
Change	5,820		1,939		16		807,970
Large Hedge Fund Advisers:							
Proposed Estimate	[7] 118,680	÷ 3 =	39,560	×	15	=	593,400
Final Estimate	[8] 139,080	÷ 3 =	46,360	×	14	=	649,040
Previously Approved	118,890	÷ 3 =	39,630	×	16	=	634,080
Change	20,190		6,730		(2)		14,960
Large Liquidity Fund Advisers:							
Proposed Estimate	[9] 72,240	÷ 3 =	24,080	×	1	=	24,080
Final Estimate	[10] 83,792	÷ 3 =	27,931	×	1	=	27,931
Previously Approved	73,200	÷ 3 =	24,400	×	1	=	24,400
Change	10,592		3,531		0		3,531
Large Private Equity Fund Advisers:							
Proposed Estimate	[11] 72,240	÷ 3 =	24,080	×	13	=	313,040
Final Estimate	[12] 102,868	÷ 3 =	34,289	×	18	=	617,202
Previously Approved	92,221	÷ 3 =	30,740	×	17	=	522,580
Change	10,647		3,549		1		94,622

Notes:

[1] We expect that the monetized time burden will be most significant for the initial report, for the same reasons discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. Accordingly, we anticipate that the initial report will require more attention from senior personnel, including compliance managers and senior risk management specialists, than will ongoing annual and quarterly filings. Changes are due to using (1) updated hours per estimates, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings, (2) updated aggregate number of, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings, and (3) updated wage estimates.

[2] For the hours per in each calculation, *see* Table 2: Annual Hour Burden Estimates for Initial Filings.

[3] We amortize the monetized time burden for initial filings over three years, as we do with other initial burdens in this PRA, because we believe that most of the burden will be incurred in the initial filing.

[4] *See* Table 2: Annual Hour Burden Estimates for Initial Filings.

[5] In the case of the proposed estimates, for smaller private fund advisers, we estimate that the initial report will most likely be completed equally by a compliance manager at a cost of $339 per hour and a senior risk management specialist at a cost of $391 per hour. (($339 per hour × 0.5) + ($391 per hour × 0.5)) × 50 hours per = $18,250.

[6] In the case of the final estimates, for smaller private fund advisers, we estimate that the initial report will most likely be completed equally by a compliance manager at a cost of $360 per hour and a senior risk management specialist at a cost of $416 per hour. (($360 per hour × 0.5) + ($416 per hour × 0.5)) × 55 hours per = $21,340.

[7] In the case of the proposed estimates, for large hedge fund advisers, we estimate that for the initial report, of a total estimated burden of 345 hours, approximately 60% will most likely be performed by compliance professionals and 40% will most likely be performed by programmers working on system configuration and reporting automation (that is approximately 207 hours for compliance professionals and approximately 138 hours for programmers). Of the work performed by compliance professionals, we anticipate that it will be performed equally by a compliance manager at a cost of $339 per hour and a senior risk management specialist at a cost of $391 per hour. Of the work performed by programmers, we anticipate that it will be performed equally by a senior programmer at a cost of $362 per hour and a programmer analyst at a cost of $263 per hour. (($339 per hour × 0.5) + ($391 per hour × 0.5)) × 207 hours = $75,555. (($362 per hour × 0.5) + ($263 per hour × 0.5)) × 138 hours = $43,125. $75,555 + $43,125 = $118,680.

[8] In the case of the final estimates, for large hedge fund advisers, we estimate that for the initial report, of a total estimated burden of 380 hours, approximately 60% will most likely be performed by compliance professionals and 40% will most likely be performed by programmers working on system configuration and reporting automation (that is approximately 228 hours for compliance professionals and approximately 152 hours for programmers). Of the work performed by compliance professionals, we anticipate that it will be performed equally by a compliance manager at a cost of $360 per hour and a senior risk management specialist at a cost of $416 per hour. Of the work performed by programmers, we anticipate that it will be performed equally by a senior programmer at a cost of $386 per hour and a programmer analyst at a cost of $280 per hour. (($360 per hour × 0.5) + ($416 per hour × 0.5)) × 228 hours = $88,464. (($386 per hour × 0.5) + ($280 per hour × 0.5)) × 152 hours = $50,616. $88,464 + $50,616 = $139,080.

[700] The hourly wage rates used in our proposed and final estimates are based on (1) SIFMA's *Management & Professional Earnings in the Securities Industry 2013,* modified by SEC staff to account for an 1,800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead; and (2) SIFMA's *Office Salaries in the Securities Industry 2013,* modified by SEC staff to account for an 1,800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead. The final estimates are based on the preceding SIFMA data sets, which SEC staff have updated since the proposing release to account for current inflation rates.

[9] In the case of the proposed estimates, for large liquidity fund advisers, we estimate that for the initial report, of a total estimated burden of 210 hours, approximately 60% will most likely be performed by compliance professionals and approximately 40% will most likely be performed by programmers working on system configuration and reporting automation (that is approximately 126 hours for compliance professionals and 84 hours for programmers). Of the work performed by compliance professionals, we anticipate that it will be performed equally by a compliance manager at a cost of $339 per hour and a senior risk management specialist at a cost of $391 per hour. Of the work performed by programmers, we anticipate that it will be performed equally by a senior programmer at a cost of $362 per hour and a programmer analyst at a cost of $263 per hour. (($339 per hour × 0.5) + ($391 per hour × 0.5)) × 126 hours = $45,990. (($362 per hour × 0.5) + ($263 per hour × 0.5)) × 84 hours = $26,250. $45,990 + $26,250 = $72,240.

[10] In the case of the final estimates, for large liquidity fund advisers, we estimate that for the initial report, of a total estimated burden of 229 hours, approximately 60% will most likely be performed by compliance professionals and approximately 40% will most likely be performed by programmers working on system configuration and reporting automation (that is approximately 137 hours for compliance professionals and 92 hours for programmers). Of the work performed by compliance professionals, we anticipate that it will be performed equally by a compliance manager at a cost of $360 per hour and a senior risk management specialist at a cost of $416 per hour. Of the work performed by programmers, we anticipate that it will be performed equally by a senior programmer at a cost of $386 per hour and a programmer analyst at a cost of $280 per hour. (($360 per hour × 0.5) + ($416 per hour × 0.5)) × 137 hours = $53,156. (($386 per hour × 0.5) + ($280 per hour × 0.5)) × 92 hours = $30,636. $53,156 + $30,636 = $83,792.

[11] In the case of the proposed estimates, for large private equity fund advisers, we expect that for the initial report, of a total estimated burden of 210 hours, approximately 60% will most likely be performed by compliance professionals and approximately 40% will most likely be performed by programmers working on system configuration and reporting automation (that is approximately 126 hours for compliance professionals and 84 hours for programmers). Of the work performed by compliance professionals, we anticipate that it will be performed equally by a compliance manager at a cost of $339 per hour and a senior risk management specialist at a cost of $391 per hour. Of the work performed by programmers, we anticipate that it will be performed equally by a senior programmer at a cost of $362 per hour and a programmer analyst at a cost of $263 per hour. (($339 per hour × 0.5) + ($391 per hour × 0.5)) × 126 hours = $45,990. (($362 per hour × 0.5) + ($263 per hour × 0.5)) × 84 hours = $26,250. $45,990 + $26,250 = $72,240.

[12] In the case of the final estimates, for large private equity fund advisers, we expect that for the initial report, of a total estimated burden of 281 hours, approximately 60% will most likely be performed by compliance professionals and approximately 40% will most likely be performed by programmers working on system configuration and reporting automation (that is approximately 169 hours for compliance professionals and 112 hours for programmers). Of the work performed by compliance professionals, we anticipate that it will be performed equally by a compliance manager at a cost of $360 per hour and a senior risk management specialist at a cost of $416 per hour. Of the work performed by programmers, we anticipate that it will be performed equally by a senior programmer at a cost of $386 per hour and a programmer analyst at a cost of $280 per hour. (($360 per hour × 0.5) + ($416 per hour × 0.5)) × 169 hours = $65,572. (($386 per hour × 0.5) + ($280 per hour × 0.5)) × 112 hours = $37,296. $65,572 + $37,296 = $102,868.

TABLE 7—ANNUAL MONETIZED TIME BURDEN OF ONGOING ANNUAL AND QUARTERLY FILINGS

Respondent [1]	Per response [2]		Aggregate number of responses		Aggregate monetized time burden
Smaller Private Fund Advisers:					
Proposed Estimate	[3] $6,040	×	[4] $2,085	=	$12,593,400
Final Estimate	[5] 7,062	×	[6] 2,376	=	16,779,312
Previously Approved	4,815	×	2,258	=	10,872,270
Change	2,247		118		5,907,042
Large Hedge Fund Advisers:					
Proposed Estimate	[7] 48,320	×	[8] 2,308	=	111,522,560
Final Estimate	[9] 56,496	×	[10] 2,224	=	125,647,104
Previously Approved	48,150	×	2,328	=	112,093,200
Change	8,346		(104)		13,553,904
Large Liquidity Fund Advisers:					
Proposed Estimate	[11] 22,650	×	[12] 92	=	2,083,800
Final Estimate	[13] 27,606	×	[14] 80	=	2,208,480
Previously Approved	22,470	×	84	=	1,887,480
Change	5,136		(4)		321,000
Large Private Equity Fund Advisers:					
Proposed Estimate	[15] 31,710	×	[16] 356	=	11,288,760
Final Estimate	[17] 46,545	×	[18] 432	=	20,107,440
Previously Approved	41,730	×	418	=	17,443,140
Change	4,815		14		2,664,300

Notes:

[1] We expect that the monetized time burden will be less costly for ongoing annual and quarterly reports than for initial reports, for the same reasons discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. Accordingly, we anticipate that senior personnel will bear less of the reporting burden than they would for the initial report. Changes are due to using (1) updated wage estimates, (2) updated hours per response estimates, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings, and (3) updated number of respondents, as discussed in Table 2: Annual Hour Burden Estimates for Initial Filings. Changes to estimates concerning large liquidity fund advisers primarily appear to be due to correcting a calculation error, as discussed below.

[2] For all types of respondents, in the case of the proposed estimates, we estimate that both annual and quarterly reports would be completed equally by (1) a compliance manager at a cost of $339 per hour, (2) a senior compliance examiner at a cost of $260, (3) a senior risk management specialist at a cost of $391 per hour, and (4) a risk management specialist at a cost of $218 an hour. ($339 × 0.25 = $84.75) + ($260 × 0.25 = $65) + ($391 × 0.25 = $97.75) + ($218 × 0.25 = $54.50) = $302. In the case of the final estimates, we estimate that both annual and quarterly reports would be completed equally by (1) a compliance manager at a cost of $360 per hour, (2) a senior compliance examiner at a cost of $276, (3) a senior risk management specialist at a cost of $416 per hour, and (4) a risk management specialist at a cost of $232 an hour. ($360 × 0.25 = $90) + ($276 × 0.25 = $69) + ($416 × 0.25 = $104) + ($232 × 0.25 = $58) = $321. To calculate the cost per response for each respondent, we used the hours per response from Table 2: Annual Hour Burden Estimates for Initial Filings.

[3] In the case of the proposed estimates, cost per response for smaller private fund advisers: ($302 per hour × 20 hours per response = $6,040 per response.)

[4] In the case of the proposed estimates, (2,085 smaller private fund advisers × 1 response annually = 2,085 aggregate responses.)

[5] In the case of the final estimates, cost per response for smaller private fund advisers: ($321 per hour × 22 hours per response = $7,062 per response.)
[6] In the case of the final estimates, (2,376 smaller private fund advisers × 1 response annually = 2,376 aggregate responses.)
[7] In the case of the proposed estimates, cost per response for large hedge fund advisers: ($302 per hour × 160 hours per response = $48,320 per response.)
[8] In the case of the proposed estimates, (577 large hedge fund advisers × 4 responses annually = 2,308 aggregate responses.)
[9] In the case of the final estimates, cost per response for large hedge fund advisers: ($321 per hour × 176 hours per response = $56,496 per response.)
[10] In the case of the final estimates, (556 large hedge fund advisers × 4 responses annually = 2,224 aggregate responses.)
[11] In the case of the proposed estimates, cost per response for large liquidity fund advisers: ($302 per hour × 75 hours per response = $22,650 per response.)
[12] In the case of the proposed estimates, (23 large liquidity fund advisers × 4 responses annually = 92 aggregate responses.)
[13] In the case of the final estimates, cost per response for large liquidity fund advisers: ($321 per hour × 86 hours per response = $27,606 per response.)
[14] In the case of the final estimates, (20 large liquidity fund advisers × 4 responses annually = 80 aggregate responses.)
[15] In the case of the proposed estimates, cost per response for large private equity fund advisers: ($302 per hour × 105 hours per response = $31,710 per response.)
[16] In the case of the proposed estimates, (356 private equity fund advisers × 1 response annually = 356 aggregate responses.)
[17] In the case of the final estimates, cost per response for large private equity fund advisers: ($321 per hour × 145 hours per response = $46,545 per response.)
[18] In the case of the final estimates, (432 private equity fund advisers × 1 response annually = 432 aggregate responses.)

TABLE 8—ANNUAL MONETIZED TIME BURDEN OF CURRENT REPORTING AND PRIVATE EQUITY EVENT REPORTING [1]

Respondent	Per response		Aggregate number of responses		Aggregate monetized time burden
Smaller Private Fund Advisers:					
Proposed Estimate	Not Applicable				
Final Estimate	$2,024	×	20	=	$40,480
Previously Approved	2,024	×	20	=	40,480
Change	0	×	0	=	0
Large Hedge Fund Advisers:					
Proposed Estimate	Not Applicable				
Final Estimate	5,160	×	60	=	309,600
Previously Approved	5,160	×	60	=	309,600
Change	0	×	0	=	0
Large Private Equity Fund Advisers:					
Proposed Estimate	Not Applicable				
Final Estimate	2,024	×	20	=	40,480
Previously Approved	2,024	×	20	=	40,480
Change	0	×	0	=	0

Note:
[1] Subsequent to the 2022 Joint Form PF Proposing Release, the SEC adopted amendments to Form PF, which added Form PF section 5 (Current report for large hedge fund advisers to qualifying hedge funds) and section 6 (Quarterly report for advisers to private equity funds) to Form PF. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4, at section V for proposed and final estimates for current reporting and private equity event reporting. We did not propose any changes to these sections in the 2022 Joint Form PF Proposing Release and are not adopting any changes to these sections in this Release.

TABLE 9—ANNUAL MONETIZED TIME BURDEN FOR TRANSITION FILINGS, FINAL FILINGS, AND TEMPORARY HARDSHIP REQUESTS

Filing type [1]	Per response		Aggregate number of responses [2]		Aggregate monetized time burden
Transition Filing from Quarterly to Annual:					
Proposed Estimate	[3] $19.25	×	68	=	$1,309
Final Estimate	[4] 20.50	×	69	=	1,414.50
Previously Approved	20.50	×	71	=	1,455.50
Change	0		(2)		(41)
Final Filings:					
Proposed Estimate	[5] 19.25	×	233	=	4,485.25
Final Estimate	[3] 20.50	×	243	=	4,981.50
Previously Approved	20.50	×	235	=	4,817.50
Change	0		8		164
Temporary Hardship Requests:					
Proposed Estimate	[7] 237.50	×	3	=	712.50
Final Estimate	[8] 252.38	×	4	=	1,009.52
Previously Approved	252.38	×	4	=	1,099.52

TABLE 9—ANNUAL MONETIZED TIME BURDEN FOR TRANSITION FILINGS, FINAL FILINGS, AND TEMPORARY HARDSHIP REQUESTS—Continued

Filing type [1]	Per response		Aggregate number of responses [2]		Aggregate monetized time burden
Change	0		0		(90)

Notes:
[1] All changes are due to using updated data concerning wage rates and the number of responses.
[2] *See* Table 5: Annual Hour Burden Estimates for Transition Filings, Final Filings, and Temporary Hardship Requests.
[3] In the case of the proposed estimates, we estimate that each transition filing will take 0.25 hours and that a compliance clerk would perform this work at a cost of $77 an hour. (0.25 hours × $77 = $19.25.)
[4] In the case of the final estimates, we estimate that each transition filing will take 0.25 hours and that a compliance clerk would perform this work at a cost of $82 an hour. (0.25 hours × $82 = $20.50.)
[5] In the case of the proposed estimates, we estimate that each final filing will take 0.25 hours and that a compliance clerk would perform this work at a cost of $77 an hour. (0.25 hours × $77 = $19.25.)
[6] In the case of the final estimates, we estimate that each final filing will take 0.25 hours and that a compliance clerk would perform this work at a cost of $82 an hour. (0.25 hours × $82 = $20.50.)
[7] In the case of the proposed estimates, we estimate that each temporary hardship request will take 1 hour. We estimate that a compliance manager would perform five-eighths of the work at a cost of $339 and a general clerk would perform three-eighths of the work at a cost of $68. (1 hour × ((⅝ of an hour × $339 = $212) + (⅜ of an hour × $68 = $25.50)) = $237.50 per response.
[8] In the case of the final estimates, we estimate that each temporary hardship request will take 1 hour. We estimate that a compliance manager would perform five-eighths of the work at a cost of $360 and a general clerk would perform three-eighths of the work at a cost of $73. (1 hour × ((⅝ of an hour × $360 = $225) + (⅜ of an hour × $73 = $27.38)) = $252.38 per response.

e. Annual External Cost Burden Estimates

Below are tables with annual external cost burden estimates for (1) initial filings, (2) ongoing annual and quarterly filings, and (3) current reporting and private equity event reporting. There are no filing fees for transition filings, final filings, or temporary hardship requests and we continue to estimate there would be no external costs for those filings, as previously approved.

TABLE 10—ANNUAL EXTERNAL COST BURDEN FOR ONGOING ANNUAL AND QUARTERLY FILINGS AS WELL AS INITIAL FILINGS

Respondent [1]	Number of responses per respondent [2]		Filing fee per filing [3]		Total filing fees	External cost of initial filing [4]		External cost of initial filing amortized over 3 years [5]		Number of initial filings [6]		Aggregate external cost of initial filing amortized over 3 years [7]	Total aggregate external cost [8]
Smaller Private Fund Advisers:													
Proposed Estimate	1	×	$150	=	$150	$10,000	÷ 3 =	$3,333	×	309	=	$1,029,897	[9] $1,388,997
Final Estimate	1	×	150	=	150	10,000	÷ 3 =	3,333	×	374	=	1,246,542	[10] 1,659,042
Previously Approved	1	×	150	=	150	Not Applicable							392,400
Change	0		0		0	Not Applicable							1,266,642
Large Hedge Fund Advisers:													
Proposed Estimate	4	×	150	=	600	50,000	÷ 3 =	16,667	×	15	=	250,005	[11] 605,205
Final Estimate	4	×	150	=	600	70,000	÷ 3 =	23,333	×	14	=	326,662	[12] 668,662
Previously Approved	4	×	150	=	600	50,000	÷ 3 =	16,667	×	16	=	266,672	625,472
Change	0		0		0	20,000		6,666		(2)		59,990	43,190
Large Liquidity Fund Advisers:													
Proposed Estimate	4	×	150	=	600	50,000	÷ 3 =	16,667	×	1	=	16,667	[13] 31,067
Final Estimate	4	×	150	=	600	50,000	÷ 3 =	16,667	×	1	=	16,667	[14] 29,267
Previously Approved	4	×	150	=	600	50,000	÷ 3 =	16,667	×	1	=	16,667	29,867
Change	0		0		0	0		0		0		0	(600)
Large Private Equity Fund Advisers:													
Proposed Estimate	1	×	150	=	150	50,000	÷ 3 =	16,667	×	13	=	216,671	[15] 272,021
Final Estimate	1	×	150	=	150	50,000	÷ 3 =	16,667	×	18	=	300,006	[16] 367,656
Previously Approved	1	×	150	=	150	50,000	÷ 3 =	16,667	×	17	=	283,339	348,589
Change	0		0		0	0		0		9		16,667	19,067

Notes:
[1] We estimate that advisers would incur the cost of filing fees for each filing. For initial filings, advisers may incur costs to modify existing systems or deploy new systems to support Form PF reporting, acquire or use hardware to perform computations, or otherwise process data that Form PF requires.
[2] Smaller private fund advisers and large private equity fund advisers file annually. Large hedge fund advisers and large liquidity fund advisers file quarterly.
[3] The SEC established Form PF filing fees in a separate order. Since 2011, filing fees have been and continue to be $150 per annual filing and $150 per quarterly filing. *See* Order Approving Filing Fees for Exempt Reporting Advisers and Private Fund Advisers, Advisers Act Release No. 3305 (Oct. 24, 2011) [76 FR 67004 (Oct. 28, 2011)].

[4] In the previous PRA submission for the rules, staff estimated that the external cost burden for initial filings would range from $0 to $50,000 per adviser. This range reflected the fact that the cost to any adviser may depend on how many funds or the types of funds it manages, the state of its existing systems, the complexity of its business, the frequency of Form PF filings, the deadlines for completion, and the amount of information the adviser must disclose on Form PF. Staff also estimated that smaller private fund advisers would be unlikely to bear such costs because the information they must provide is limited and will, in many cases, already be maintained in the ordinary course of business. Given the proposed amendments, we estimate that the external cost burden for smaller private fund advisers would range from $0 to $10,000, per smaller private fund adviser. This range reflects the amendments and is designed to reflect that the cost to any smaller private fund adviser may depend on how many funds or the type of funds it manages, the state of its existing systems, and the complexity of its business. We use the upper range to calculate the estimate for smaller private fund advisers: $10,000. Also, given the amendments, in our proposed estimates, we estimated that the external cost burden for initial filings for large hedge fund advisers, large liquidity fund advisers, and large private equity fund advisers would continue to range from $0 to $50,000 for the same reasons as the current estimates for those types of advisers. We used the upper range to calculate the estimates: $50,000. After considering comments we received, we estimate a range from $0 to $70,000 for large hedge fund advisers. We use the upper range to calculate cost burden for initial filings for large hedge fund advisers estimates: $70,000. We continue to estimate that the external cost burden for initial filings for large liquidity fund advisers, and large private equity fund advisers would continue to range from $0 to $50,000 for the same reasons as the current estimates for those types of advisers. We used the upper range to calculate the estimates: $50,000.

[5] We amortize the external cost burden of initial filings over three years, as we do with other initial burdens in this PRA, because we believe that most of the burden will be incurred in the initial filing.

[6] *See* Table 2: Annual Hour Burden Estimates for Initial Filings.

[7] Changes to the aggregate external cost of initial filings, amortized over three years are due to (1) the proposed amendments and (2) using updated data.

[8] Changes to the total aggregate external cost are due to (1) the amendments, (2) using updated data, (3) the amendments to Form PF adopted subsequent to the 2022 Joint Form PF Proposing Release, and (4) comments we received to our estimates.

[9] In the case of the proposed estimates, Private Funds Statistics show 2,394 smaller private fund advisers filed Form PF in the third quarter of 2021. (2,394 smaller private fund advisers × $150 total filing fees) + $1,029,897 aggregate external cost of initial filing amortized over three years = $1,388,997 total aggregate external cost.

[10] In the case of the final estimates, Private Funds Statistics show 2,750 smaller private fund advisers filed Form PF in the first quarter of 2023. (2,750 smaller private fund advisers × $150 total filing fees) + $1,246,542 aggregate external cost of initial filing amortized over three years = $1,659,042 total aggregate external cost.

[11] In the case of the proposed estimates, Private Funds Statistics show 592 large hedge fund advisers filed Form PF in the third quarter of 2021. (592 large hedge fund advisers × $600 total filing fees) + $250,005 aggregate external cost of initial filing amortized over three years = $605,205 total aggregate external cost.

[12] In the case of the final estimates, Private Funds Statistics show 570 large hedge fund advisers filed Form PF in the first quarter of 2023. (570 large hedge fund advisers × $600 total filing fees) + $326,662 aggregate external cost of initial filing amortized over three years = $668,662 total aggregate external cost.

[13] In the case of the proposed estimates, Private Funds Statistics show 24 large liquidity fund advisers filed Form PF in the third quarter of 2021. (24 large liquidity fund advisers × $600 total filing fees) + $16,667 aggregate external cost of initial filing amortized over three years = $31,067 total aggregate external cost.

[14] In the case of the final estimates, Private Funds Statistics show 21 large liquidity fund advisers filed Form PF in the first quarter of 2023. (21 large liquidity fund advisers × $600 total filing fees) + $16,667 aggregate external cost of initial filing amortized over three years = $29,267 total aggregate external cost.

[15] In the case of the proposed estimates, Private Funds Statistics show 369 large private equity fund advisers filed Form PF in the third quarter of 2021. (369 large private equity fund advisers × $150 total filing fees) + $216,671 aggregate external cost of initial filing amortized over three years = $272,021 total aggregate external cost.

[16] In the case of the final estimates, Private Funds Statistics show 450 large private equity fund advisers filed Form PF in the first quarter of 2023. (450 large private equity fund advisers × $150 total filing fees) + $300,006 aggregate external cost of initial filing amortized over three years = $367,506 total aggregate external cost.

TABLE 11—ANNUAL EXTERNAL COST BURDEN FOR CURRENT REPORTING AND PRIVATE EQUITY EVENT REPORTING [1]

Respondent	Aggregate number of responses		Cost of outside counsel per current report or private equity event report		Aggregate cost of outside counsel	One-time cost of system changes	Total aggregate external cost
Smaller Private Fund Advisers:							
Proposed Estimate	Not Applicable						
Final Estimate	20	×	$1,695	=	$33,900	$15,000	$48,900
Previously Approved	20	×	1,695	=	33,900	15,000	48,900
Change	0		0		0	0	0
Large Hedge Fund Advisers:							
Proposed Estimate	Not Applicable						
Final Estimate	60	×	1,695	=	101,700	15,000	116,700
Previously Approved	60	×	1,695	=	101,700	15,000	116,700
Change	0		0		0	0	0
Large Private Equity Fund Advisers:							
Proposed Estimate	Not Applicable						
Final Estimate	20	×	1,695	=	33,900	15,000	48,900
Previously Approved	20	×	1,695	=	33,900	15,000	48,900
Change	0		0		0	0	0

Advisers pay filing fees, the amount of which will be determined in a separate action.

Note:

[1] Subsequent to the 2022 Joint Form PF Proposing Release, the SEC adopted amendments to Form PF, which added Form PF section 5 (Current report for large hedge fund advisers to qualifying hedge funds) and section 6 (Quarterly report for advisers to private equity funds) to Form PF. *See* May 2023 SEC Form PF Amending Release, *supra* footnote 4, at section V for proposed and final estimates for current reporting and private equity event reporting. We did not propose any changes to these sections in the 2022 Joint Form PF Proposing Release and are not adopting any changes to these sections in this Release.

f. Summary of Estimates and Change in Burden

TABLE 12—AGGREGATE ANNUAL ESTIMATES

Description [1]	Proposed estimates	Final estimates	Previously approved	Change
Respondents	3,379 respondents [2]	3,791 respondents [3]	3,671 respondents	120 respondents.[4]
Responses	5,483 responses [5]	5,935 responses [6]	5,907 responses	28 responses.[7]
Time Burden	463,296 hours [8]	524,376 hours [9]	451,012 hours	73,364 hours.
Monetized Time Burden (Dollars).	$140,305,194 [10]	$169,094,737.02 [11]	$145,721,172.52	$23,373,564.50.
External Cost Burden (Dollars).	$2,297,290 [12]	$2,938,977 [13]	$1,610,828	$1,328,149.

Notes:

[1] Changes are due to (1) the amendments, (2) using updated data, and (3) in the case of the final estimates subsequent Form PF amendments adopted after the 2022 Joint Form PF Proposing Release and comments we received to our estimates, as described in this PRA.

[2] In the case of the proposed estimates, Private Funds Statistics show the following advisers filed Form PF in the third quarter of 2021: 2,394 smaller private fund advisers + 592 large hedge fund advisers + 24 large liquidity fund advisers + 369 large private equity fund advisers = 3,379 advisers.

[3] In the case of the final estimates, Private Funds Statistics show the following advisers filed Form PF in the first quarter of 2023: 2,750 smaller private fund advisers + 570 large hedge fund advisers + 21 large liquidity fund advisers + 450 large private equity fund advisers = 3,791 advisers.

[4] Changes are due to using updated data.

[5] In the case of the proposed estimates, for initial filings (Table 2): (309 smaller private fund adviser responses + 15 large hedge fund adviser responses + 1 large liquidity fund adviser response + 13 large private equity fund adviser responses = 338 responses.) For ongoing annual and quarterly filings (Table 7): (2,085 smaller private fund adviser responses + 2,308 large hedge fund adviser responses + 92 large liquidity fund adviser responses + 356 large private equity fund adviser responses = 4,841 responses.) (338 responses for initial filings + 4,841 responses for ongoing annual and quarterly filings + 68 responses for transition filings + 233 responses for final filings + 3 responses for temporary hardship requests = 5,483 responses.)

[6] In the case of the final estimates, for initial filings (Table 2): (374 smaller private fund adviser responses + 14 large hedge fund adviser responses + 1 large liquidity fund adviser response + 18 large private equity fund adviser responses = 407 responses.) For ongoing annual and quarterly filings (Table 7): (2,376 smaller private fund adviser responses + 2,224 large hedge fund adviser responses + 80 large liquidity fund adviser responses + 432 large private equity fund adviser responses = 5,112 responses.) For current reporting and private equity event reporting (Table 8): (20 smaller private fund adviser responses + 60 large hedge fund adviser responses + 20 large private equity fund adviser responses = 100 responses) (407 responses for initial filings + 5,112 responses for ongoing annual and quarterly filings + 100 responses + 69 responses for transition filings + 243 responses for final filings + 4 responses for temporary hardship requests = 5,935 responses.)

[7] Changes are due to using updated data concerning the number of filers and, in the case of the final estimates, the inclusion of current reporting and private equity event reporting, which was adopted after the 2022 Joint Form PF Proposing Release, and comments we received to our estimates.

[8] In the case of the proposed estimates, for initial filings: (5,253 hours for smaller private fund advisers + 1,725 hours for large hedge fund advisers + 70 hours for large liquidity fund advisers + 910 hours for large private equity fund advisers = 7,958 hours). For ongoing annual and quarterly filings: (41,700 hours for smaller private fund advisers + 369,280 hours for large hedge fund advisers + 6,900 for hours large liquidity fund advisers + 37,380 hours for large private equity fund advisers = 455,260 hours). (7,958 hours for initial filings + 455,260 for ongoing annual and quarterly filings + 17 hours for transition filings + 58.25 hours for final filings + 3 hours for temporary hardship requests = 463,296 hours.

[9] In the case of the final estimates, for initial filings: (6,732 hours for smaller private fund advisers + 1,778 hours for large hedge fund advisers + 76 hours for large liquidity fund advisers + 1,692 hours for large private equity fund advisers = 10,278 hours). For ongoing annual and quarterly filings: (52,272 hours for smaller private fund advisers + 391,424 hours for large hedge fund advisers + 6,880 for hours large liquidity fund advisers + 62,640 hours for large private equity fund advisers = 513,216 hours). For current reporting and private equity event reporting: (100 hours for smaller private fund adviser + 600 hours for large hedge fund adviser + 100 hours for large private equity fund adviser = 800 hours) (10,278 hours for initial filings + 513,216 for ongoing annual and quarterly filings + 800 hours for current reporting and private equity event reporting + 17.25 hours for transition filings + 60.75 hours for final filings + 4 hours for temporary hardship requests = 524,376 hours.

[10] In the case of the proposed estimates, for initial filings: ($1,879,647 for smaller private fund advisers + $593,400 for large hedge fund advisers + $24,080 for large liquidity fund advisers + $313,040 for large private equity fund advisers = $2,810,167). For ongoing annual and quarterly filings: ($12,593,400 for smaller private fund advisers + $111,522,560 for large hedge fund advisers + $2,083,800 for large liquidity fund advisers + $11,288,760 for large private equity fund advisers = $137,488,520). ($2,810,167 for initial filings + $137,488,520 for ongoing annual and quarterly filings + $1,309 for transition filings + $4,485.25 for final filings + $712.50 for temporary hardship requests = $140,305,194.

[11] In the case of the final estimates, for initial filings: ($2,660,262 for smaller private fund advisers + $649,040 for large hedge fund advisers + $27,931 for large liquidity fund advisers + $617,202 for large private equity fund advisers = $3,954,435). For ongoing annual and quarterly filings: ($16,779,312 for smaller private fund advisers + $125,647,104 for large hedge fund advisers + $2,208,480 for large liquidity fund advisers + $20,107,440 for large private equity fund advisers = $164,742,336). For current reporting and private equity event reporting: ($40,480 for smaller private equity fund advisers + $309,600 for large hedge fund advisers + $40,480 for large private equity fund advisers = $390,560). ($3,954,435 for initial filings + $164,742,336 for ongoing annual and quarterly filings + $390,560 for current reporting and private equity event reporting + $1,414.50 for transition filings + $4,982 for final filings + $1,009.52 for temporary hardship requests = $169,094,737.02.

[12] In the case of the proposed estimates, for the external cost burden: $1,388,997 for smaller private fund advisers + $605,205 for large hedge fund advisers + $31,067 for large liquidity fund advisers + $272,021 for large private equity fund advisers = $2,297,290.

[13] In the case of the final estimates, for external cost burden for annual, quarterly, and initial filing ($1,659,042 for smaller private fund advisers + $668,662 for large hedge fund advisers + $29,267 for large liquidity fund advisers + $367,506 for large private equity fund advisers = $2,724,477). For current reporting: ($48,900 for smaller private fund advisers + $116,700 for large hedge funds + $48,900 for large private equity fund advisers = $214,500). $2,724,477 + $214,500 = $2,938,977.

VI. Regulatory Flexibility Act Certification

CFTC

The Regulatory Flexibility Act (''RFA'') requires that when Federal agencies publish a proposed rulemaking pursuant to section 553 of the Administrative Procedure Act, they consider whether the final rule will have a significant economic impact on a substantial number of ''small entities.'' [701]

Registered CPOs and CTAs that are dually registered as investment advisers with the SEC are only required to file Form PF with the SEC pursuant to the Advisers Act. While CFTC rule 4.27(d) provides that dually registered CPOs and CTAs that file Form PF with the SEC will be deemed to have filed Form PF with the CFTC, for purposes of any enforcement action regarding any false or misleading statement of material fact in Form PF, the CFTC is not imposing any additional obligation herein beyond what is already required of these entities when filing Form PF with the SEC.

Entities impacted by the Form PF are the SEC's regulated entities and no small entity on its own would meet the

[701] 5 U.S.C. 601, *et. seq.*

Form PF's minimum reporting threshold of $150 million in regulatory assets under management attributable to private funds. Also, any economic impact imposed by Form PF on small entities registered with both the CFTC and the SEC has been accounted for within the SEC's regulatory flexibility analysis regarding the impact of this collection of information under the RFA. Accordingly, the Chairman, on behalf of the CFTC, hereby certifies pursuant to 5 U.S.C. 605(b) that the final rules will not have a significant economic impact on a substantial number of small entities.

SEC

Pursuant to section 605(b) of the Regulatory Flexibility Act of 1980 (''Regulatory Flexibility Act''),[702] the SEC certified that the proposed amendments to Advisers Act rule 204(b)–1 and Form PF would not, if adopted, have a significant economic impact on a substantial number of small entities. The SEC included this certification in section V of the 2022 Joint Form PF Proposing Release. As discussed in more detail in the 2022 Joint Form PF Proposing Release, for the purposes of the Advisers Act and the Regulatory Flexibility Act, an investment adviser generally is a small entity if it (1) has assets under management having a total value of less than $25 million, (2) did not have total assets of $5 million or more on the last day of the most recent fiscal year, and (3) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had total assets of $5 million or more on the last day of its most recent fiscal year.[703]

By definition, no small entity on its own would meet rule 204(b)–1 and Form PF's minimum reporting threshold of $150 million in regulatory assets under management attributable to private funds. Based on Form PF and Form ADV data as of December 2022, the SEC estimates that no small entity advisers are required to file Form PF. The SEC does not have evidence to suggest that any small entities are required to file Form PF but are not filing Form PF. Therefore, the SEC stated in the 2022 Joint Form PF Proposing Release there would be no significant economic impact on a substantial number of small entities from the proposed amendments to Advisers Act rule 204(b)–1 and Form PF.

The SEC requested comment on its certification in section V of the 2022 Joint Form PF Proposing Release. While some commenters addressed the potential impact of the proposed amendments on smaller or mid-size private funds,[704] no commenters responded to this request for comment regarding the SEC's certification. We are adopting the amendments largely as proposed, with certain modifications from the proposal, as discussed more fully above in section II, that do not affect the Advisers Act rule 204(b)–1 and Form PF's minimum reporting threshold. We do not believe that these changes alter the basis upon which the certification in the 2022 Joint Form PF Proposing Release was made. Accordingly, the SEC certifies that the final amendments to Advisers Act rule 204(b)–1 and Form PF will not have a significant economic impact on a substantial number of small entities.

Statutory Authority

CFTC

The CFTC authority for this rulemaking is provided by 15 U.S.C. 80b–11.

SEC

The SEC is amending 17 CFR 275.204(b)–1 pursuant to its authority set forth in sections 204(b) and 211(e) of the Advisers Act [15 U.S.C. 80b–4 and 15 U.S.C. 80b–11], respectively.

The SEC is amending 17 CFR 279.9 pursuant to its authority set forth in sections 204(b) and 211(e) of the Advisers Act [15 U.S.C. 80b–4 and 15 U.S.C. 80b–11], respectively.

List of Subjects in 17 CFR Parts 275 and 279

Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 1. The general authority citation for part 275 continues to read as follows.

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

■ 2. Amend § 275.204(b)–1 by:

■ a. Revising paragraph (f)(2)(i) by removing the phrases ''in paper format,'' and '', Item A of Section 1a and Section 5 of Form PF, checking the box in Section 1a indicating that you are requesting a temporary hardship exemption'';

■ b. Redesignating paragraph (f)(4) as paragraph (f)(5); and

■ c. Adding new paragraph (f)(4).

The addition reads as follows:

§ 275.204(b)–1 Reporting by investment advisers to private funds.

* * * * *

(f) * * *

(4) A request for a temporary hardship exemption is considered filed upon the earlier of the date the request is postmarked or the date it is received by the Commission.

* * * * *

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

■ 3. The authority citation for part 279 continues to read as follows:

Authority: The Investment Advisers Act of 1940, 15 U.S.C. 80b–1, *et seq.,* Pub. L. 111–203, 124 Stat. 1376.

§ 279.9 Form PF, reporting by investment advisers to private funds.

■ 4. Revise Form PF (referenced in § 279.9).

Note: Form PF is attached as Appendix A to this document. Form PF will not appear in the Code of Federal Regulations.

By the Commissions.

Dated: February 8, 2024.

Christopher Kirkpatrick,

Secretary, Commodity Futures Trading Commission.

Vanessa A. Countryman,

Secretary, Securities and Exchange Commission.

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

BILLING CODE 8011–01–P

[702] 5 U.S.C. 601, *et. seq.*

[703] 17 CFR 275.0–7.

[704] *See, e.g.,* AIC Comment Letter I; AIMA/ACC Comment Letter; USCC Comment Letter.

Appendix A—Form PF

FORM PF (Paper Version)

Reporting Form for Investment Advisers to Private Funds and Certain Commodity Pool Operators and Commodity Trading Advisors

OMB APPROVAL	
OMB Number:	3235-0679
Expires:	[Date]
Estimated average burden hours per response:	[XX.XX]

Form PF: General Instructions

Read these instructions carefully before completing Form PF. Failure to follow these instructions, properly complete Form PF, or pay all required fees may result in your Form PF being delayed or rejected.

In these instructions and in Form PF, "you" means the *private fund adviser* completing or amending this Form PF. If you are a "separately identifiable department or division" (SID) of a bank, "you" means the SID rather than the bank (except as provided in Question 1(a)). Terms that appear in *italics* are defined in the Glossary of Terms to Form PF.

1. Who must complete and file a Form PF?

You must complete and file a Form PF, if:

A. You are registered or required to register with the *SEC* as an investment adviser;

OR

You are registered or required to register with the *CFTC* as a *CPO* or *CTA* and you are also registered or required to register with the *SEC* as an investment adviser;

AND

B. You manage one or more *private funds*.

AND

C. You and your *related persons*, collectively, had at least $150 million in *private fund assets under management* as of the last day of your most recently completed fiscal year.

Many *private fund advisers* meeting these criteria will be required to complete only Section 1 of Form PF and will need to file only on an annual basis. *Large private fund advisers*, however, will be required to provide additional data, and *large hedge fund advisers* and *large liquidity fund advisers* will need to file every quarter. *Large hedge fund advisers* will need to file a current report in Section 5 and advisers to *private equity funds* will need to file a current report in Section 6, upon certain *current reporting events*. See Instructions 3, 9, and 12 below.

For purposes of determining whether you meet the reporting threshold, you are not required to include the *regulatory assets under management* of any *related person* that is *separately operated*. See Instruction 5 below for more detail.

If your *principal office and place of business* is outside the United States, for purposes of this Form PF you may disregard any *private fund* that, during your last fiscal year, was not a *United States person*, was not offered in the United States, and was not beneficially owned by any *United States person*.

2. I have a *related person* who is required to file Form PF. May I and my *related person* file a single Form PF?

Related persons may (but are not required to) report on a single Form PF information with respect

to all such *related persons* and the *private funds* they advise. You must identify in your response to Question 1 the *related persons* as to which you are reporting and, where information is requested about you or the *private funds* you advise, respond as though you and such *related persons* were one *firm*.

3. How is Form PF organized?

Section 1 – All Form PF filers

Section 1a All *private fund advisers* required to file Form PF must complete Section 1a. Section 1a asks general identifying information about you and the types of *private funds* you advise.

Section 1b All *private fund advisers* required to file Form PF must complete Section 1b. Section 1b asks for certain information regarding the *private funds* that you advise.

Section 1c All *private fund advisers* that are required to file Form PF and advise one or more *hedge funds* must complete Section 1c. Section 1c asks for certain information regarding the *hedge funds* that you advise.

Section 2 – *Large hedge fund advisers*

Section 2 If you and your *related persons*, collectively, had at least $1.5 billion in *hedge fund assets under management* as of the last day of any month in the fiscal quarter immediately preceding your most recently completed fiscal quarter, you must complete a separate Section 2 with respect to each *qualifying hedge fund* that you advise. You are not required to include the *regulatory assets under management* of any *related person* that is *separately operated*.

In addition, you must complete a separate Section 2 for each *parallel fund* that is part of a *parallel fund structure* that, in the aggregate, comprises a *qualifying hedge fund* (even if that *parallel fund* is not itself a *qualifying hedge fund*); and you must complete a separate Section 2 for the *master fund* of any *master-feeder arrangement* that, in the aggregate, comprises a *qualifying hedge fund* (even if that *master fund* is not itself a *qualifying hedge fund*) in accordance with Instruction 6.

Section 3 – *Large liquidity fund advisers*

Section 3 You are required to complete Section 3 if (i) you advise one or more *liquidity funds* and (ii) as of the last day of any month in the fiscal quarter immediately preceding your most recently completed fiscal quarter, you and your *related persons*, collectively, had at least $1 billion in *combined money market and liquidity fund assets under management*. You are not required to include the *regulatory assets under management* of any *related person* that is *separately operated*.

You must complete a separate Section 3 with respect to each *liquidity fund* that you advise.

Section 4 – *Large private equity fund advisers*

Section 4 — You are required to complete Section 4 if you and your *related persons*, collectively, had at least $2 billion in *private equity fund assets under management* as of the last day of your most recently completed fiscal year. You are not required to include the *regulatory assets under management* of any *related person* that is *separately operated*.

You must complete a separate Section 4 with respect to each *private equity fund* that you advise.

Section 5 – *Current report* for *large hedge fund advisers* to *qualifying hedge funds*

Section 5 — Section 5 is the current reporting form for *large hedge fund advisers* to *qualifying hedge funds*. You must complete and file Section 5 for any *current reporting event* with respect to a *qualifying hedge fund* you advise.

Section 6 – *Quarterly event report* for advisers to *private equity funds*

Section 6 — Section 6 is the quarterly event reporting form about *private equity funds*. You must complete and file Section 6 for any *private equity reporting event* with respect to a *private equity fund* you advise.

Section 7 – Advisers requesting a temporary hardship exemption

Section 7 — See Instruction 14 for details.

4. I am a subadviser or engage a subadviser for a private fund. Who is responsible for reporting information about that private fund?

Only one *private fund adviser* should complete and file Form PF for each *private fund*. If the adviser that filed *Form ADV Section 7.B.1* with respect to any *private fund* is required to file Form PF, the same adviser must also complete and file Form PF for that *private fund*. If the adviser that filed *Form ADV Section 7.B.1* with respect to any *private fund* is not required to file Form PF (e.g., because it is an *exempt reporting adviser*) and one or more other advisers to the fund is required to file Form PF, another adviser must complete and file Form PF for that *private fund*.

Where a question requests aggregate information regarding the *private funds* that you advise, you should only include information regarding the *private funds* for which you are filing Section 1b of Form PF.

5. For purposes of determining whether I meet any reporting threshold, when am I required to aggregate information regarding parallel funds, parallel managed accounts, master-feeder arrangements, and funds managed by related persons?

- You must aggregate any *private funds* that are part of the same *master-feeder arrangement* (even if you did not, or were not permitted to, aggregate these *private funds* for purposes of *Form ADV Section 7.B.1*).
- You must aggregate any *private funds* that are part of the same *parallel fund structure.*
- Any *dependent parallel managed account* must be aggregated with the largest *private fund* to which that *dependent parallel managed account* relates.
- You must treat any *private fund* or *parallel managed account* advised by any of your *related persons* as though it were advised by you (including *related persons* that you have not identified in Question 1(b) as *related persons* for which you are filing Form PF, though you may exclude *related persons* that are *separately operated).* Where you are aggregating *dependent parallel managed accounts* to determine whether you meet a reporting threshold, assets held in the accounts should be treated as assets of the *private funds* with which they

are aggregated.

6. How do I report information regarding parallel funds, parallel managed accounts, master-feeder arrangements, and funds reported by related persons?

You must separately report each component fund of *master-feeder arrangements* and *parallel fund structures.* However:

- Do not report a *feeder fund* that invests all of its assets in (i) a single *master fund*, (ii) U.S. treasury bills, and/or (iii) *cash and cash equivalents (i.e.,* a disregarded *feeder fund*). In reporting a *master fund,* you must identify whether each *feeder* fund is a disregarded *feeder fund* in Question 7 and "look through" to any disregarded *feeder funds'* investors in responding to Questions 21 – 22, 51 – 53, and 59 – 64.
- Do not report information regarding *parallel managed accounts* (except in Question 16).
- Report information for any *private fund* advised by any of your *related persons* unless you have identified that *related person* in Question 1(b) as a *related person* for which you are filing Form PF.

Example 1. You advise a *master-feeder arrangement* with two *feeder funds*. *Feeder fund X* has invested $500 in the *master fund* and holds a *foreign exchange derivative* with a notional value of $100. *Feeder fund* Y invests $200 in the *master fund* and has no other assets or liabilities, except cash. The *master fund* has used the $700 received from the *feeder funds* to invest in *corporate bonds*. None of these funds has any other assets or liabilities.

For purposes of determining whether any of the funds comprises a *qualifying hedge fund*, this *master-feeder arrangement* should be treated as a single *private fund* whose only investments are $700 in *corporate bonds* and a *foreign exchange derivative* with a notional value of $100.

For reporting purposes, if the aggregated *master-feeder arrangement* comprises a *qualifying hedge fund,* the *master fund* is reported as a *qualifying hedge fund* (complete Section 2 (even if is not a *qualifying hedge* fund by itself) and report *feeder fund X* and *feeder fund Y* as *internal private fund* investors in Question 7).

A separate report for *feeder fund* X is required because the fund holds assets in addition to its investment in the *master fund* and *cash and cash equivalents* (complete Section 1b and 1c). Further, if *feeder fund* X meets the threshold to be a *qualifying hedge fund,* it also must be reported as a *qualifying hedge fund* (complete Section 2 and Section 5, as applicable). In determining the *feeder fund*'s reporting threshold, you should include all assets and liabilities of the *feeder fund*, except for any assets invested in the *master fund*.
A separate report is not required for *feeder fund* Y because it invests in a single *master fund* and has no other assets or liabilities except cash.

Example 2. You advise a *parallel fund structure* consisting of two *hedge funds*, named *parallel fund* A and *parallel fund* B. You also advise a related *dependent parallel managed account*. The account and each fund have invested in *corporate bonds* of Company X and have no other assets or liabilities. The value of *parallel fund* A's investment is $400, the value of *parallel fund* B's investment is $300 and the value of the *dependent parallel*

managed account's investment is $200. For purposes of determining whether either of the *parallel funds* is a *qualifying hedge fund*, the entire *parallel fund structure* and the related *dependent parallel managed account* should be treated as a single *private fund* whose only asset is $900 of *corporate bonds* issued by Company X.

For reporting purposes, both *parallel fund* A and *parallel fund* B must be reported separately (for each of *parallel fund* A and B, complete Sections 1b and 1c, Section 2, and Section 5, as applicable, if the *parallel fund structure* is a *qualifying hedge fund).* Y ou would disregard the value of the investment by the *dependent parallel managed account* when reporting for *parallel fund* A and B, and instead, report the value of that investment ($200) in Question 16 for the largest *parallel fund, parallel fund A*.

7. I advise a *private fund* that invests in other *private funds* (e.g., a "fund of funds") or trading vehicles. How should I treat these investments for purposes of Form PF?

Reporting thresholds. You must include the value of *private fund* investments in other *private funds* in determining whether you are required to file Form PF and whether you meet thresholds for filing as a *large hedge fund adviser*, *large liquidity fund adviser,* or *large private equity fund adviser* and whether a *reporting fund* is a *qualifying hedge fund.*

Funds that invest 80% or more of their assets in other *private funds*. If you advise a *private fund* that (i) invests 80% or more of its assets in the equity of *private funds* (including *internal private funds and external private funds*) and (ii) aside from such *private fund* investments, holds only *cash and cash equivalents* and instruments acquired for the purpose of hedging currency exposure, then you are only required to complete Section 1b for that fund.

Trading vehicles. If the *reporting fund* holds assets, incurs leverage, or conducts trading or other activities through a *trading vehicle,* you must identify the *trading vehicle* in Section 1b, Question 7(b), and report answers on an aggregated basis for the *reporting fund* and such *trading vehicle*. You must include (look through to) the *trading vehicle*'s holdings, adjusted for the *reporting fund's* percentage ownership of the *trading vehicle*, for all questions answered by the *reporting fund*.

Responding to questions. Except as otherwise provided in the instructions for a particular question in Form PF, include the *value* of a *reporting fund's* investments in other *private funds* (both *internal and external)* in responding to questions under this Form PF. For example, (i) include the *value* of the *reporting fund's* investments in other *private funds* in reporting *gross asset value* and *net asset value* in Question 11 and 12, but (ii) exclude the *value* of a *reporting fund's* investment in other private funds in Question 3, the instructions to which explain that you must not include the *value* of a *reporting fund's* investments in other *internal private funds* in responding to the question.

Do not "look through" the *reporting fund's* investments in *internal private funds* or *external private funds* (other than a *trading vehicle* as explained above) in responding to questions on the Form, unless the question instructs you to report exposure obtained indirectly through positions in such funds or other entities. For example, do not look through to the creditors of or counterparties to other *private funds* in responding to questions that ask about a *reporting fund's borrowing* and counterparty exposure (*e.g.,* Questions 18, 26, 27, and 28). However, selected questions in Section 2 of the Form require you to report indirect exposure resulting from positions held through other entities including *private funds,* and you must "look through" the *reporting fund's* investments in *internal private funds* and *external private funds* in responding to these questions. (See Question 32, Question 33, Question 35, Question 36,and Question 47.) If you cannot avoid "looking through" to the *reporting fund's* investments in *internal private funds* or *external private funds* in responding to a particular question, provide an explanation in Question 4.

Solely for purposes of this Instruction 7, you may treat as a *private fund* any issuer formed under the laws of a jurisdiction other than the United States that has not offered or sold its securities in the United States or to *United States persons* but that would be a *private fund* if it had engaged in such an offering or sale.

8. I advise a *private fund* that invests in funds or other entities that are not *private funds* or *trading vehicles*. How should I treat these investments for purposes of Form PF?

Include the *value* of investments in any fund or other entity for all purposes under this Form PF. For example, you must include the value of these investments in determining reporting thresholds and responding to questions. For example, include the value of these investments in determining *gross asset value* in Question 11 and net asset value in Question 12.

Except for *trading vehicles*, do not "look through" a *reporting fund's* investments in any fund or other entity, unless the question instructs you to report exposure obtained indirectly through positions in such funds or other entities. For example, do not "look through" to the creditors of or counterparties to any fund or other entity in responding to questions that ask about a *reporting fund's borrowing* and counterparty exposure (*e.g.,* Questions 18, 26, 27, and 28). However, selected questions in Section 2 of the Form require you to report indirect exposure resulting from positions held through entities, such as a fund or other entity, and you must "look through" the *reporting fund's* investments such funds or other entities in responding to these questions. (See Question 32, Question 33, Question 35, Question 36, and Question 47). You should "look through" *trading vehicles* for all questions as provided in Instruction 7.

9. When am I required to update Form PF?

You are required to update Form PF at the following times:

Periodic filings (large hedge fund advisers)	Within 60 calendar days after the end of each calendar quarter, you must file a *quarterly update* that updates the answers to all Items in this Form PF relating to the *hedge funds* that you advise. If your fiscal year does not end at the end of a calendar quarter, you must file a *quarterly update* that updates the answers to all Items in this Form PF within 60 days after the end of the next calendar quarter after your fiscal year end. You may, however, submit an initial filing for the next calendar quarter after your fiscal year end that updates information relating only to the *hedge funds* that you advise so long as you amend your Form PF within 120 calendar days after the end of your fiscal year to update information relating to any other *private funds* that you advise. When you file such an amendment, you are not required to update information previously filed for such quarter.
Periodic filings (large liquidity fund advisers)	Within 15 calendar days after the end of each calendar quarter, you must file a *quarterly update* that updates the answers to all Items in this Form PF relating to the *liquidity funds* that you advise. If your fiscal year does not end at the end of a calendar quarter, you must file a *quarterly update* that updates the answers to all Items in this Form PF within 15 days after the end of the next calendar quarter after your fiscal year end. You may, however, submit an initial filing for the next calendar quarter

	after your fiscal year end that updates information relating only to the *liquidity funds* that you advise so long as you amend your Form PF within 120 calendar days after the end of your fiscal year to update information relating to any other *private funds* that you advise (subject to the next paragraph). When you file such an amendment, you are not required to update information previously filed for such quarter. If you are both a *large liquidity fund adviser* and a *large hedge fund adviser*, you must file your *quarterly updates* with respect to the *liquidity funds* that you advise within 15 calendar days and with respect to the *hedge funds* you advise within 60 calendar days.
Periodic filings (all other advisers)	Within 120 calendar days after the end of your fiscal year, you must file an *annual update* that updates the answers to all Items in this Form PF. *Large hedge fund advisers* and *large liquidity fund advisers* are not required to file *annual updates* but instead file *quarterly updates* for the next calendar quarter after their fiscal year end.
Transition filing	If you are transitioning from quarterly to annual filing because you are no longer a *large hedge fund adviser* or *large liquidity fund adviser*, then you must complete and file Item A of Section 1a and check the box in Section 1a indicating that you are making your final quarterly filing. You must file your transition filing no later than the last day on which your next *quarterly update* would be timely.
Current reports (large hedge fund advisers)	*Large hedge fund advisers* must file a *current report* in Section 5 upon certain *current reporting events* with respect to *qualifying hedge funds* they advise. See Section 5 for filing deadlines.
Private equity event reports (all advisers to private equity funds)	All advisers to *private equity funds* must file a *private equity event report* in Section 6 upon certain *private equity reporting events* with respect to *private equity funds* they advise within 60 calendar days after the end of each fiscal quarter.
Final filing	If you are no longer required to file Form PF, then you must complete and file Item A of Section 1a and check the box in Section 1a indicating that you are making your final filing. You must file your final filing no later than the last day on which your next Form PF update would be timely. This applies to all Form PF filers.

Failure to update your Form PF as required by these instructions is a violation of *SEC* and, where applicable, *CFTC* rules and could lead to revocation of your registration.

10. How do I obtain *private fund* identification numbers for my *reporting funds*?

Each *private fund* must have an identification number for purposes of reporting on *Form ADV* and Form PF. *Private fund* identification numbers can only be obtained by filing *Form ADV*.

If you need to obtain a *private fund* identification number and you are required to file a *quarterly update* of Form PF prior to your next annual update of *Form ADV*, then you must acquire the identification number by filing an other-than-annual amendment to your *Form ADV* and following the instructions on Form ADV for generating a new number. When filing an other-than-annual amendment for this purpose, you must complete and file all of *Form ADV Section 7.B.1* for the new *private fund*.

See Instruction 6 to Part 1A of *Form ADV* for additional information regarding the acquisition and use of *private fund* identification numbers.

11. Who must sign my Form PF or update?

The individual who signs the Form PF depends upon your form of organization: For a sole proprietorship, the sole proprietor.

- For a partnership, a general partner.
- For a corporation, an authorized principal officer.
- For a limited liability company, a managing member or authorized person.
- For a SID, a principal officer of your bank who is directly engaged in the management, direction, or supervision of your investment advisory activities.
- For all others, an authorized individual who participates in managing or directing your affairs.

The signature does not have to be notarized and should be a typed name.

If you and one or more of your *related persons* are filing a single Form PF, then Form PF may be signed by one or more individuals; however, the individual, or the individuals collectively, must have authority, as provided above, to sign both on your behalf and on behalf of all such *related persons*.

12. How do I file my Form PF?

You must file Form PF electronically through the Form PF filing system on the Investment Adviser Registration Depository website (www.iard.com), which contains detailed filing instructions. Questions regarding filing through the Form PF filing system should be addressed to the Financial Industry Regulatory Authority (FINRA) at 240-386-4848.

If you are a *large hedge fund adviser* filing a current report in Section 5, only file Section 5. Do not file any other sections of the Form. If you are an adviser to *private equity funds* filing a current report in Section 6 only file Section 6. Do not file any other sections of the Form. For all other types of filings, file the applicable sections as provided in Instruction 3.

13. Are there filing fees?

Yes, you must pay a filing fee for your Form PF filings. The Form PF filing fee schedule is published at http://www.sec.gov/iard and http://www.iard.com.

14. What if I am not able to file electronically?

A temporary hardship exemption is available if you encounter unanticipated technical difficulties that prevent you from making a timely filing with the Form PF filing system, such as a computer malfunction or electrical outage. This exemption does not permit you to file on paper; instead, it extends the deadline for an electronic filing for seven "business days" (as such term is used in *SEC* rule 204(b)-1(f)).

To request a temporary hardship exemption, you must complete and file on paper Item A of Section 1a and Section 7 of Form PF, checking the box in Section 1a indicating that you are requesting a temporary hardship exemption. Do not complete or file any other sections of Form PF. Mail one manually signed original and one copy of your exemption filing to: U.S. Securities and Exchange Commission, Investment Adviser Regulation Office, Mail Stop 0-25, 100 F Street NE, Washington, DC 20549 or submit electronically your signed exemption filing in PDF format by email to FormPF@sec.gov. You must preserve in your records a copy of any temporary hardship exemption

filing. Any request for a temporary hardship exemption must be filed no later than one business day after the electronic Form PF filing was due. For more information, see *SEC* rule 204(b)-1(f).

15. May I rely on my own methodologies in responding to Form PF? How should I enter requested information?

You may respond to this Form using your own internal methodologies and the conventions of your service providers, provided the information is consistent with information that you report internally and to current and prospective investors. However, your methodologies must be consistently applied, and your responses must be consistent with any instructions or other guidance relating to this Form. You may explain any of your methodologies, including related assumptions, in Question 4.

In responding to Questions on this Form, the following guidelines apply unless otherwise specifically indicated:

- provide the requested information as of the close of business on the *data reporting date*;
- if information is requested for any month or quarter, provide the requested information as of the close of business on the last calendar day of the month or quarter, respectively;
- if a question requests information expressed as a percentage, enter the response as a percentage (not a decimal) rounded to the nearest one hundredth of one percent;
- if a question requests a monetary value, provide the information in U.S. dollars as of the *data reporting date* (or other requested date), rounded to the nearest thousand, using a foreign exchange rate for the applicable date;
- if a question requests a monetary value for transactional data that covers a reporting period, provide the information in U.S. dollars, rounded to the nearest thousand, using foreign exchange rates as of the dates of any transactions to convert local currency values to U.S. dollars (see questions 14, 23(c)(iv)(B), 23(c)(iv)(C), 23(c)(iv)(D), 29, 30(a), and 34);
- if a question requests a numerical value other than a percentage or a dollar value, provide information rounded to the nearest whole number;
- if a question requests information regarding a "position" or "positions," treat two or more legs of a transaction even if offsetting or partially offsetting, or even if entered into with the same counterparty under the same master agreement as two separate positions, even if reported internally as part of a larger transaction. However, exclude closed-out positions that are closed out with the same counterparty provided that there is no credit or market exposure to the *reporting fund*;
- if a question requires you to distinguish long positions from short positions, classify positions as follows: a long position experiences a gain when the price of the market factor to which it relates increases (and/or the yield of that factor decreases), and a short position experiences a loss when the price of the market factor to which it relates increases (and/or the yield of that factor decreases);
- do not net long and short positions;
- for derivatives (other than *interest rate derivatives* and options), "value" means *gross notional value*; for *interest rate derivatives, value* means the *10-year bond equivalent*; for options, "value" means delta adjusted notional value (expressed as a *10-year bond equivalent* for options

that are *interest rate derivatives*); in determining the "value" of derivatives positions, do not net long and short positions or offsetting or partially offsetting trades; but exclude closed-out positions that are closed out with the same counterparty provided that there is no credit or market exposure to the *reporting fund*;

- for all other investments and for all *borrowings* where the *reporting fund* is the creditor, "*value*" means market value or, where there is not a readily available market value, fair value; for *borrowings* where the *reporting fund* is the debtor, "*value*" means the value you report internally and to current and prospective investors; and
- for question 25, the numerator you use to determine the percentage of *net asset value* should be measured on the same basis as *gross asset value*. Your response to this question may total more than 100%.

16. How do I amend Form PF, for example, to make a correction?

If you discover that information you filed on Form PF was not accurate at the time of filing, you may correct the information by re-filing and checking the box in Section 1a, Section 5, or Section 6, as applicable, indicating that you are amending a previously submitted filing. You are not required to update information that you believe in good faith properly responded to Form PF on the date of filing even if that information is subsequently revised for purposes of your recordkeeping, risk management or investor reporting (such as estimates that are refined after completion of a subsequent audit).

Large hedge fund advisers and *large liquidity fund advisers* that comply with their fourth quarter filing obligations by submitting an initial filing followed by an amendment in accordance with Instruction 9 will not be viewed as affirming responses regarding one fund solely by providing updated information regarding another fund at a later date.

17. How may I preserve on Form PF the anonymity of a *private fund* that I advise?

If you seek to preserve the anonymity of a *private fund* that you advise by maintaining its identity in your books and records in numerical or alphabetical code, or similar designation, pursuant to rule 204-2(d), you may identify the *private fund* on Form PF using the same code or designation in place of the fund's name.

18. How should I treat a *commodity pool* for purposes of Form PF?

Commodity pools should be treated as *hedge funds* for purposes of Form PF. If you are reporting on Form PF regarding a *commodity pool* that is not a *private fund*, then you may treat it as a *private fund* for purposes of Form PF. However, such a *commodity pool* is not required to be included when determining whether you exceed one or more reporting thresholds. If such a *commodity pool* is a *qualifying hedge fund* and you are otherwise required to report information in section 2 of Form PF, then you must report regarding the *commodity pool* in section 2 of Form PF.

Federal Information Law and Requirements for a Collection of Information

Section 204(b) of the *Advisers Act* [15 U.S.C.80b-4(b)] authorizes the *SEC* to collect the information that Form PF requires. The information collected on Form PF is designed to facilitate the Financial Stability Oversight Council's ("FSOC") monitoring of systemic risk in the private fund industry and to assist FSOC in determining whether and how to deploy its regulatory tools with respect to nonbank financial companies. The *SEC* and *CFTC* may also use information collected on Form PF in their regulatory programs, including examinations, investigations and investor protection efforts relating to private fund advisers. Filing Form PF is mandatory for advisers that satisfy the criteria described in Instruction 1 to the Form. *See also* 17 CFR 275.204(b)-1. The *SEC* does not intend to make public information reported on Form PF that is identifiable to any particular adviser or *private fund*, although the *SEC* may use Form PF information in an enforcement action. *See* Section

204(b) of the *Advisers Act*.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. The Office of Management and Budget has reviewed this collection of information under 44 U.S.C. 3507. Any member of the public may direct any comments concerning the accuracy of the burden estimate and any suggestion for reducing this burden to: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

Form PF Section 1a	**Information about you and your *related persons*** (to be completed by all Form PF filers)

Section 1a: Information about you and your *related persons*

Check the box that indicates what you would like to do:

a. If you are not a *large hedge fund adviser* or *large liquidity fund adviser*:

- ☐ Submit your first filing on Form PF
  for the period ended:
- ☐ Submit an *annual update*
  for the period ended:
- ☐ Amend a previously submitted filing
  for the period ended:
- ☐ Submit a final filing
- ☐ Request a temporary hardship exemption

b. If you are a *large hedge fund adviser* or *large liquidity fund adviser*:

- ☐ Submit your first filing on Form PF
  for the [1st, 2nd, 3rd, 4th] quarter, which ended:
- ☐ Submit a *quarterly update* (including fourth quarter updates)
  for the [1st, 2nd, 3rd, 4th] quarter, which ended:
- ☐ Amend a previously submitted filing
  for the [1st, 2nd, 3rd, 4th] quarter, which ended:
- ☐ Transition to annual reporting
- ☐ Submit a final filing
- ☐ Request a temporary hardship exemption

Item A. Information about you

1. (a) Provide your name and the other identifying information requested below.

(This should be your full legal name. If you are a sole proprietor, this will be your last, first, and middle names. If you are a SID*, enter the full legal name of your bank.*

Please use the same name that you use in your Form ADV*.)*

Legal name	SEC 801-Number	*NFA* ID Number, if any	Large trader ID, if any	Large trader ID suffix, if any	*LEI*, if any

(b) Provide the following information for each of the *related persons*, if any, with respect to which you are reporting information on this Form PF:

Legal name	SEC 801-Number	*NFA* ID Number, if any	Large trader ID, if any	Large trader ID suffix, if any	*LEI*, if any

(c) Provide the following information for yourself and each of the *related persons*, if any, with respect to which you are reporting information on this Form PF that is registered or required to be registered as a *CPO* and/or *CTA:*

Legal Name	CPO, CTA, or Both
	[Drop-down list]
	[Drop-down list]

2. Signatures of sole proprietor or authorized representative *(see Instruction 11 to Form PF)*. Signature on behalf of the *firm* and its *related persons:*

I, the undersigned, sign this Form PF on behalf of, and with the authority of, the *firm*. In addition, I sign this Form PF on behalf of, and with the authority of, each of the *related persons* identified in Question 1(b) (other than any *related person* for which another individual has signed this Form PF below).

To the extent that Section 1 or 2 of this Form PF is filed in accordance with a regulatory obligation imposed by *CEA* rule 4.27, the *firm*, each *related person* for which I am signing this Form PF, and I shall accept that any false or misleading statement of a material fact therein or material omission therefrom shall constitute a violation of section 6(c)(2) of the *CEA*.

Name of individual:	
Signature:	
Title:	
Email address:	
Telephone contact number (include area code and, if outside the United States, country code):	
Date:	

Signature on behalf of *related persons:*

I, the undersigned, sign this Form PF on behalf of, and with the authority of, the *related person(s)* identified below.

To the extent that Section 1 or 2 of this Form PF is filed in accordance with a regulatory obligation imposed by *CEA* rule 4.27, each *related person* identified below and I shall accept that any false or misleading statement of a material fact therein or material omission therefrom shall constitute a violation of section 6(c)(2) of the *CEA*.

Name of each *related person* on behalf of which this individual is signing:	
Name of individual:	
Signature:	
Title:	
Email address:	
Telephone contact number (include area code and, if outside the United States, country code):	
Date:	

Item B. Information about assets of *private funds* that you advise

3. Provide a breakdown of your *regulatory assets under management* and your *net assets under management* as follows:

(If you are filing a quarterly update *for your first, second or third fiscal quarter, you are only required to update row (a), in the case of a* large hedge fund adviser*, or row (b), in the case of a* large liquidity fund adviser*. To avoid double counting, do not include the* value *of your* private funds*' investments in other* internal private funds.*)*

	Regulatory assets under management	***Net assets under management***
(a) *Hedge funds*		
(b) *Liquidity funds*		
(c) *Private equity funds*		
(d) *Real estate funds*		
(e) *Securitized asset funds*		
(f) *Venture capital funds*		
(g) *Other private funds*		
(h) Funds and accounts other than *private funds* (i.e., the remainder of your assets under management).....		

Item C. Miscellaneous

4. You may use the space below to explain any assumptions that you made in responding to any question in this Form PF. Assumptions must be in addition to, or reasonably follow from, any instructions or other guidance relating to Form PF. If you are aware of any instructions or other guidance that may require a different assumption, provide a citation and explain why that assumption is not appropriate for this purpose. To the extent responses relate to a particular question, provide the Question number(s), as applicable.

5.

Question number	**Description**
[drop-down list for question number or "all" options.]	

Form PF Section 1b	Information about the *private funds* you advise (to be completed by all Form PF filers)

Section 1b: Information about the *private funds* you advise

You must complete a separate Section 1b for each *private fund* that you advise, except as provided by Instruction 6.

Item A. *Reporting fund* identifying information

5. (a) Name of the *reporting fund*	
(b) *Private fund* identification number of the *reporting fund*	
(c) *NFA* identification number of the *reporting fund*, if applicable	
(d) *LEI* of the *reporting fund*, if any	

6. (a) For purposes of reporting on this Form PF, what type of fund is the *reporting fund*? [Select one]

[drop-down list for *hedge fund that is not a qualifying hedge fund, qualifying hedge fund*, *liquidity fund*, *private equity fund*, *real estate fund*, *securitized asset fund*, *venture capital fund,* or "other."]

If you identify the reporting fund as "other," describe the reporting fund in Question 4, including why it would not qualify for any of the other selections. If you identify the reporting fund as a different type of fund on Form ADV*, explain why in Question 4.*

(b) Is the *reporting fund* a *commodity pool*?

☐ Yes ☐ No

(c) Does the *reporting fund* operate as a *UCITS*?

☐ Yes ☐ No

(d) If you checked yes in (c), in what countries does the *reporting fund* operate as a *UCITS*?

[Drop-down list]

(e) Does the *reporting fund* operate as an *AIF*?

☐ Yes ☐ No

(f) If you checked yes in (e), in what countries does the *reporting fund* operate as an *AIF*?

[Drop-down list]

(g) Does the *reporting fund* offer itself as a money market fund outside the United States?

☐ Yes ☐ No

(h) If you checked yes in (g), in what countries does the *reporting fund* offer itself as a money market fund? [Drop-down list]

(*For the purposes of responding to Question 6(g) and 6(h) only, a money market fund includes a similar fund that operates outside of the United States in accordance with applicable non-U.S. laws and are not limited to "money market funds" as defined in the Glossary of Terms.)*

7. (a) Is the *reporting fund* the *master fund* of a *master-feeder arrangement*? If so, check "yes" below, and complete (i) and (ii) for each *feeder fund*. Otherwise, check "no." *See Instructions 5, 6, and 7 for information on treatment of* master-feeder arrangements.

☐ Yes ☐ No

(i) Name of *feeder fund*.....

(ii) *Private fund* identification number of the *feeder fund* .....

(iii) Is the *feeder fund* a separate *reporting fund*? If so, check "yes," below. If the *feeder fund* is a "disregarded" *feeder fund* in accordance with Instruction 6, check "no."

☐ Yes ☐ No

(b) Do any *internal private funds* (other than the *feeder funds* identified in (a) above) invest in the *reporting fund*? If so, check "yes" and complete (i), (ii), and (iii) for each such *internal private fund*. Otherwise, check "no."

☐ Yes ☐ No

(i) Name of *internal private fund*….....

(ii) *Internal private fund's LEI*, if it has one.....

(iii) *Private fund* identification number of the *internal private fund*....

8. (a) Is the *reporting fund* a component of a *parallel fund structure*? If so, check "yes" below. Otherwise, check "no." (See Instructions 5 and 6 for information regarding the treatment of *parallel funds.)*

☐ Yes ☐ No

If you responded "yes" to Question 8(a), complete (b) through (e) below for each component in the *parallel fund structure*.

(b) Name of the *parallel fund*	
(c) *Private fund* identification number of the *parallel fund*	
(d) *NFA* identification number of the *parallel fund*, if applicable	
(e) *LEI* of the *parallel fund*, if any	

9. If the *reporting fund* holds assets, incurs leverage, or conducts trading or other activities through a *trading vehicle*, provide the following information about each *trading vehicle*.

(a) Legal name .....

(b) *LEI, if any*.....

(c) Other identifying information (indicate type used, if applicable. *E.g., RSSD ID*)……

(d) Does the *reporting fund* hold assets through the *trading vehicle*?

☐ Yes ☐ No

(e) Does the *reporting fund* incur leverage through the *trading vehicle*?

☐ Yes ☐ No

(f) Does the *reporting fund* conduct trading or other activities through the *trading vehicle*?

☐ Yes ☐ No

10. (a) Is the *reporting fund* an *open-end private fund*?

☐ Yes ☐ No

(b) Is the *reporting fund* a *closed-end private fund*?

☐ Yes ☐ No

(If you responded "no" to both question 10(a) and question 10(b), please provide a detailed explanation in question 4.)

(c) If you responded "*yes*" to 10(a), indicate whether withdrawals/redemptions are permitted most commonly (*i.e.* with respect to most investors) (regardless of whether there are notice requirements, "gates," lock-ups, or other restrictions on withdrawals/redemptions). (check one):

☐ on any business day

☐ at intervals of least two business days and up to a month

☐ at intervals longer than monthly up to quarterly

☐ at intervals longer than quarterly up to annually

☐ at intervals of more than one year

(d) If you responded "*yes*" to 10(a), indicate, as of the *data reporting date*, what percentage of the *reporting fund's net asset value*, if any:

(i) May be subjected to a suspension of investor withdrawals/redemptions by an adviser or fund governing body *(this question relates to an adviser's or governing body's right to suspend and not just whether a suspension is currently effective)*.....	
(ii) May be subjected to material restrictions on investor withdrawals/ redemptions (e.g., "gates") by an adviser or fund governing body *(this question relates to an adviser's or governing body's right to impose a restriction and not just whether a restriction has been imposed)*	
(iii) Is subject to a suspension of investor withdrawals/redemptions *(this question relates to whether a suspension is currently effective and not just an adviser's or governing body's right to suspend)*.....	
(iv) Is subject to a material restriction on investor withdrawals/redemptions (e.g., a "gate") *(this question relates to whether a restriction has been imposed and not just an adviser's or governing body's right to impose a restriction)*.....	

(For Question 10(d), please note that the standards for imposing suspensions and restrictions on withdrawals/redemptions may vary among funds. Make a good faith determination of the provisions that would likely be triggered during conditions that you view as significant market stress.)

Item B. Assets, financing, and investor concentration

11.

	Date	*Gross Asset Value or Gross Reporting fund Aggregate Calculated Value*
(a) *Gross asset value* of the *reporting fund* as of the end of the *reporting period*.....	[Drop-down list of month, day, year]	
(b) If you are filing a *quarterly update*, provide the *reporting fund's gross asset value* if available, or *gross reporting fund aggregate calculated value* if the *gross asset value* is not available, as of the end of the first month of the *reporting period*……..	[Drop-down list of month, day, year]	
(c) If you are filing a *quarterly update*, provide the *reporting fund's gross asset value* if available, or *gross reporting fund aggregate calculated value* if the *gross asset* value is not available, as of the end of the second month of the *reporting period*……	[Drop-down list of month, day, year]	

(The amount of the gross asset value *of the reporting fund as of the end of the reporting period may differ from the amount you reported in response to question 11 of Form ADV Section 7.B.1. For instance, the amounts may not be the same if you are filing Form PF on a quarterly basis or because you may not aggregate a master-feeder arrangement for purposes of this Form PF.)*

(For a feeder fund, the gross asset value and gross reporting fund aggregate calculated value calculations should be inclusive of its equity holdings in the master fund, along with its other holdings).

(d) Is the value reported in Question 11(b) above a *gross reporting fund aggregate calculated value*?

☐ Yes ☐ No

(e) Is the value reported in Question 11(c) above a *gross reporting fund aggregate calculated value*?

☐ Yes ☐ No

12.

	Date	*Net Asset Value or Reporting fund Aggregate Calculated Value*
(a) *Net asset value* of the *reporting fund* as of the end of the *reporting period*.....	[Drop-down list of month, day, year]	
(b) If you are filing a *quarterly update*, provide the *reporting fund's net asset value* if available or, *reporting fund aggregate calculated value* if the *net asset value* is not available, as of the end of the first month of the *reporting period*……..	[Drop-down list of month, day, year]	
(c) If you are filing a *quarterly update*, provide the *reporting fund's net asset value* if available or, *reporting fund aggregate calculated value* if the *net asset value* is not available, as of the end of the second month of the *reporting period*……	[Drop-down list of month, day, year]	

(For a feeder fund, the net asset value and net reporting fund aggregate calculated value calculations should be inclusive of its equity holdings in the master fund, along with its other holdings).

(d) Is the value reported in Question 12(b) above a *reporting fund aggregate calculated value*?

☐ Yes ☐ No

(e) Is the value reported in Question 12(c) above a *reporting fund aggregate calculated value*?

☐ Yes ☐ No

13. *Value* of *unfunded commitments* included in *gross asset value* or *gross reporting fund aggregate calculated value* and *net asset value* or *reporting fund aggregate calculated value* reported in Questions 11 and 12 (if the *reporting fund* does not contract for *unfunded commitments*, enter "NA")…….

14. Provide the following information concerning the *reporting fund's* activity during the *reporting period.*

(For the purpose of this question, contributions include all new contributions from investors, but exclude contributions of committed capital that you have already included in gross asset value *calculated in accordance with Form ADV, Part 1A, Instruction 6.e.(3). Withdrawals and redemptions from the reporting fund include all withdrawals, redemptions and other distributions of any kind to investors.)*

(If you are filing a quarterly update, *provide this information for* each month *of the reporting period.)*

(a) Contributions to the *reporting fund* during the *reporting period*…….....

(b) Withdrawals and redemptions from the *reporting fund* during the *reporting period*…

15. (a) Value of *reporting fund's* investments in equity of *external private funds:* _____

(b) Check "yes" if the *reporting fund* is a *feeder fund* in a *master-feeder arrangement* and complete the

information below for the *master fund* in which this fund invests. Otherwise, check "no."

☐ Yes ☐ No

(i) Name of *master fund*……

(ii) *Private fund* identification number of the *master fund:*……

(iii) The *master fund's LEI*, if any……

(iv) *Value* of the *private fund's* investments in equity of the *master fund:*……

(c) Check "yes" if the *reporting fund* invests in any *internal private funds* and complete the information below for each such *internal private fund*. Otherwise, check "no." Do not complete (c)(i) through (c)(iv) for a *master fund* identified in (b), above.

☐ Yes ☐ No

(i) Name of *internal private fund*….

(ii) Private fund identification number of the *internal private fund*……

(iii) The *internal private fund's LEI*, if any……

(iv) *Value* of the *private fund's* investments in equity of the *internal private fund:*

16. Value of all *parallel managed accounts* related to the *reporting fund:* _____

(If any of your parallel managed accounts *relates to more than one of the* private funds *you advise, only report the value of the account once, in connection with the largest* private fund *to which it relates)*

17. What is the *reporting fund's* base currency?
[drop-down list of currencies]
Other _____

18. Provide the following information regarding the *value* of the *reporting fund's borrowings* and the types of creditors.

(You are not required to respond to this question for any reporting fund with respect to which you are answering questions in Section 2 or Question 71 in Section 4. Do not net out amounts that the reporting fund loans to creditors or the value of collateral pledged to creditors.)

(The percentages borrowed from the specified types of creditors should add up to approximately 100%.)

(a) Dollar amount of total *borrowings*	
(b) Percentage borrowed from *U.S. depository institutions*	
(c) Percentage borrowed from U.S. creditors that are not *U.S. depository institutions*	
(d) Percentage borrowed from non-U.S. creditors	

19. (a) Does the *reporting fund* have any outstanding derivatives positions?

☐ Yes ☐ No

(b) If you responded "yes" to Question 19(a), provide the aggregate *value* of all derivatives positions of the *reporting fund*……

20. Provide a summary of the *reporting fund's* assets and liabilities categorized using the hierarchy below and indicate the date as of which this categorization was performed. For assets and liabilities that you report internally and to current and prospective investors as representing fair value, or for which you are

required to determine fair value in order to report the *reporting fund's* regulatory assets under management on *Form ADV*, categorize them into the following categories based on the valuation assumptions utilized:

Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 – Other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs, such as your assumptions or the fund's assumptions used to determine the fair value of the asset or liability.

For any assets and liabilities that you report internally and to current and prospective investors as representing a measurement attribute other than fair value, and for which you are not required to determine fair value in order to report the *reporting fund's* regulatory assets under management on *Form ADV*, separately report these assets and liabilities in the "cost-based" measurement column.

Do not report *cash and cash equivalents* in any other column except for the *cash and cash equivalents column*.

(If the fund's financial statements are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") or another accounting standard that requires the categorization of assets and liabilities using a fair value hierarchy similar to that established under U.S. GAAP, then respond to this question using the fair value hierarchy established under the applicable accounting standard. Report the absolute value of all liabilities. If you report assets as a negative value, you must provide an explanation in Question 4.)

(You should use the estimated values for the fiscal year for which you are reporting if the audit of the financial statement is not yet completed when the Form PF is required to be filed and explain that the information is an estimate in Question 4. You may, but are not required to, amend when the audited financial statements are complete.)

(This question requires the use of fair values and cost-based measurements, which may be different from the values contemplated by Instruction 15. You are only required to respond to this question if you are filing an annual update *or a* quarterly update *for your fourth fiscal quarter.)*

As of date [drop-down box for month, day, year]

	Level 1	Level 2	Fair Value Level 3	Cost-based	*Cash and Cash Equivalents*
Assets					
Liabilities					

21. Specify the approximate percentage of the *reporting fund's* equity that is beneficially owned by the five beneficial owners having the largest equity interests in the *reporting fund.*_____

(For purposes of this question, if you know that two or more beneficial owners of the reporting fund are affiliated *with each other, you should treat them as a single beneficial owner. If the reporting fund is the* master fund *in a master-feeder arrangement, include the beneficial owners of a disregarded feeder fund described by Instruction 6 as beneficial owners of the reporting fund.)*

22. Specify the approximate percentage of the *reporting fund's* equity that is beneficially owned by the following groups of investors. If you select "other," describe in Question 4 the type of investor, why it would not qualify for any of the other groups, and any other information to explain your selection.

(Include each investor in only one group. The total should add up to approximately 100%. With respect to beneficial interests outstanding prior to March 31, 2012, that have not been transferred on or after that date, you may respond to this question using good faith estimates based on data currently available to you. If the reporting fund is the master fund in a master-feeder arrangement, include the beneficial owners of a disregarded feeder fund described by

Instruction 6 as beneficial owners of the reporting fund.)

(a) Individuals that are *United States persons* (including their trusts).....

(b) Individuals that are not *United States persons* (including their trusts).....

(c) Broker-dealers that are *United States persons*.....

(d) Broker-dealers that are not *United States persons*.....

(e) Insurance companies that are *United States persons*.....

(f) Insurance companies that are not *United States persons*.....

(g) Investment companies registered with the *SEC*.....

(h) *External private funds*.....

(i) *Internal private funds*.....

(j) Non-profits that are *United States persons*.....

(k) Non-profits that are not *United States persons*.....

(l) U.S. pension plans (excluding governmental pension plans).....

(m) Non-U.S. pension funds (plans and funds that are not U.S. private or governmental pension plans.....

(n) Banking or thrift institutions that are *United States persons*.....

(o) Banking or thrift institutions that are not *United States persons*.....

(p) U.S. state or municipal *government entities* (excluding governmental pension plans) .....

(q) U.S. state or municipal governmental pension plans.....

(r) Sovereign wealth funds and foreign official institutions (excluding pension funds).

(s) Investors that are not *United States persons* and about which the foregoing beneficial ownership information is not known and cannot reasonably be obtained because the beneficial interest is held through a chain involving one or more third-party intermediaries .....

(t) Other .....

Item C. *Reporting fund* performance

23. Complete (a) unless the *reporting fund's* performance is reported to current and prospective investors, counterparties, or otherwise, as an *internal rate of return* since inception, in which case, complete (b). The *reporting fund* may report performance as either a time-weighted return or a money-weighted return, such as an *internal rate of return*; however, the methodology used for reporting performance should be consistent over time.

(a) Provide the *reporting fund's* gross and net performance, as reported to current and prospective investors, counterparties, or otherwise. Report the data using the *reporting fund*'s base currency. Do not calculate the *reporting fund's* performance using *reporting fund aggregate calculated value*.

If the fund reports different performance results to different groups, provide the most representative results and explain your selection in Question 4. You are required to provide monthly and quarterly performance results only if such results are calculated for the *reporting fund* (whether for purposes of reporting to current or prospective investors, counterparties, or

otherwise).

If you are submitting an initial filing or an *annual update*, complete (i) through (xvi) (concerning monthly and quarterly data), only if you calculate such results, and complete (xvii) (concerning yearly data). (For example, if you are submitting an initial filing or an *annual update* and you do not calculate monthly or quarterly performance results, complete (xvii) only.)

If you are submitting a *quarterly update*, complete the following:

- Complete (i) through (iii) (concerning monthly data), if you calculate such results; and

- Complete (xiii) through (xvi) for the applicable quarter. (For example, if you are filing a *quarterly update* for the first quarter of *reporting funds'* fiscal year, complete (xiii) (concerning the first quarter), but do not complete (xiv) (concerning the second quarter), (xv) (concerning the third quarter), or (xvi) (concerning the fourth quarter); and

- Complete (xvii) (data concerning the *reporting fund's* most recently completed fiscal year) only if the *quarterly update* is for the fourth quarter of *reporting fund's* fiscal year. If the *quarterly update* is not the fourth quarter of the *reporting fund's* fiscal year, do not complete (xvii).

(If your fiscal year is different from the reporting fund's fiscal year, then for any portion of the reporting fund's fiscal year that has not been completed as of the data reporting date, provide the relevant information from that portion of the reporting fund's preceding fiscal year.)

(Performance results for monthly and quarterly periods should not be annualized. If any period precedes the date of the fund's formation, enter "NA". You are not required to include performance results for any period with respect to which you previously provided performance results for the reporting fund on Form PF.)

	End date [drop-down list of month, day, year]	**Gross performance**	**Net of management fees, incentive fees, and allocations**
Monthly Data			
(i) 1st month of *reporting period*			
(ii) 2nd month of *reporting period*			
(iii) 3rd month of *reporting period*			
(iv) 4th month of *reporting period*			
(v) 5th month of *reporting period*			
(vi) 6th month of *reporting period*			
(vii) 7th month of *reporting period*			
(viii) 8th month of *reporting period*			
(ix) 9th month of *reporting period*			
(x) 10th month of *reporting period*			
(xi) 11th month of *reporting period*			
(xii) 12th month of *reporting period*			
Quarterly Data			
(xiii) First quarter of *reporting fund's* fiscal year			
(xiv) Second quarter of *reporting fund's* fiscal year			
(xv) Third quarter of *reporting fund's* fiscal year			
(xvi) Fourth quarter of *reporting fund's* fiscal year			
Yearly Data			
(xvii) *Reporting fund's* most recently completed fiscal year			

(b) If the *reporting fund's* performance is reported to current and prospective investors, counterparties, or otherwise, as an *internal rate of return* since inception, provide the *reporting fund*'s performance below. If such information is reported to current and prospective investors, counterparties, or otherwise, in a currency other than U.S. dollars, report the data using that currency, and identify the currency in Question 4. Do not calculate the *reporting fund's* performance using a *reporting fund aggregate calculated value*.

If the fund reports different performance results to different groups, provide the most representative results and explain your selection in Question 4. You are required to provide quarterly performance results since inception only if such results are calculated for the *reporting fund* (whether for purposes of reporting to current and prospective investors, counterparties, or otherwise). Internal rates of return for periods longer than one year must be annualized, while internal rates of return for periods one year or less must not be annualized.

(i) Inception date used for *internal rate of return* calculation:.....

(ii) Inception through the first quarter of *reporting fund's* fiscal year…….....

(iii) Inception through the second quarter of *reporting fund's* fiscal year…….....

(iv) Inception through the third quarter of *reporting fund's* fiscal year…….....

(v) Inception through the end of the *reporting fund's* most recently completed fiscal year……

(vi) Does the reported *internal rate of return* include the effect of any *borrowings* secured by *unfunded commitments* (i.e. subscription lines of credit)?

☐ Yes ☐ No

(c) If you calculate a market value on a daily basis for any position in the *reporting fund's* portfolio, report the following:(i) Provide the *reporting fund aggregate calculated value* at the end of the *reporting period,* and if you are filing a *quarterly update,* also report the *reporting fund aggregate calculated value* as of the end of the first and second month of the *reporting period.*(ii) Provide the *reporting fund's* volatility of the natural log of the *daily rate-of-return* for each month of the *reporting period*, computed as the standard deviation of the natural log of one plus each of the *daily rates-of-return* in the month, annualized by the square root of 252 trading days. When calculating the natural log of a *daily rate-of-return*, the *rate of return*, which is expressed as a percent, must first be converted to a decimal value and then one must be added to the decimal value.

	Annualized volatility of returns
(A) 1st month of *reporting period*	
(B) 2nd month of *reporting period*	
(C) 3rd month of *reporting period.*	
(D) 4th month of *reporting period*	
(E) 5th month of *reporting period*	
(F) 6th month of *reporting period*	
(G) 7th month of *reporting period*	
(H) 8th month of *reporting period*	
(I) 9th month of *reporting period*	
(J) 10th month of *reporting period*	
(K) 11th month of *reporting period*	
(L) 12th month of *reporting period*	

(iii) Is the *reporting fund's* volatility of the *daily rates-of-return* reported to current and prospective investors, counterparties, or otherwise using a different computation than Question 23(c)(ii)? If yes, describe it in Question 4.

☐ Yes ☐ No

(iv)*(A)* Did the *reporting fund* have a negative *daily rates-of-return* for one or more days during the *reporting period*?

☐ Yes ☐ No

(B) If you responded "yes" to (iv)(*A*), report the following for the most recent peak to trough drawdown:

Amount in base currency _____ % in base currency ___ Beginning Date_____ End Date_____

If the drawdown was continuing on the *data reporting date*, do not enter an end date and check here ☐

(C) Largest peak to trough drawdown of the *reporting fund* over the *reporting period*:

Amount in base currency _____ % in base currency ___ Beginning Date_____ End Date_____

If the drawdown was continuing on the *data reporting date*, check here ☐

(D) Largest single day drawdown of the *reporting fund* over the *reporting period:*

Amount in base currency _____ % in base currency ___ Date_____

(E) Number of days with a negative *daily rates-of-return* in the *reporting period* _____.

Form PF Section 1c	Information about the *hedge funds* you advise (to be completed by all Form PF filers that advise *hedge funds*)

Section 1c: Information about the *hedge funds* you advise

You must complete a separate Section 1c for each *hedge fund* that you advise, except as provided by Instruction 6 and Instruction 7.

Item A. *Reporting fund* identifying information

24. (a) Name of the *reporting fund*.....

(b) *Private fund* identification number of the *reporting fund*.....

Item B. Certain information regarding the *reporting fund*

25. Indicate which of the investment strategies in the drop-down menu below best describe the *reporting fund's* strategies on the last day of the *reporting period*. For each strategy that you have selected, provide a good faith estimate of the percentage of the *reporting fund's net asset value* represented by that strategy. If, in your view, the *reporting fund's* allocation among strategies is appropriately represented by the percentage of deployed capital, you may also provide that information.

(Select the investment strategies that best describe the reporting fund's strategies, even if the descriptions below do not precisely match your characterization of those strategies; select "other" only if a strategy that the reporting fund uses is significantly different from any of the strategies identified below.)

(The strategies in the drop-down menu below are mutually exclusive (i.e., do not report the same assets under multiple strategies). The reporting strategies methodology used should be consistent over time. If providing percentages of capital, the total should add up to approximately 100%.) (If you select "other" as an investment strategy for the reporting fund, describe in Question 4 the investment strategy, why it would not qualify for any of the other categories, and any other information to explain the selection "other." If a particular strategy could be classified as both a digital asset strategy and another strategy, report the strategy as the non-digital asset strategy.)

Strategy	% of NAV (required)	% of capital (optional)
[drop-down menu]		

Form PF Section 1c	**Information about the *hedge funds* you advise** (to be completed by all Form PF filers that advise *hedge funds*)

26. Consolidated Counterparty Exposure Table

Report in the *consolidated counterparty exposure table* below the *reporting fund's borrowing and collateral received (B/CR)* and *lending and posted collateral (L/PC)* aggregated across all creditors and counterparties (including all *CCPs*) in U.S. dollars as of the end of the *reporting period*. *(You are not required to complete this question if the reporting fund is a* qualifying hedge fund *and you complete the* consolidated counterparty exposure table *in Section 2).*

You must net the *reporting fund's* exposure with each counterparty and among affiliated entities of a counterparty to the extent such exposures may be contractually or legally set-off or netted across those entities or one *affiliate* guarantees or may otherwise be obligated to satisfy the obligations of another under the agreements governing the transactions. Netting must be used to reflect net cash borrowed from or lent to a counterparty but must not be used to offset securities borrowed and lent against one another, when reporting prime brokerage and repo/reverse repo transactions.

Report the counterparty exposures of *trading vehicles* owned by the *reporting fund* based on the *reporting fund*'s percentage ownership of each *trading vehicle*, without netting the *trading vehicle*'s exposures with the *reporting fund*'s exposures if they are not guaranteed by the *reporting fund* or contractual obligations of the *reporting fund*. If the *reporting fund* guarantees or is contractually obligated to fulfill obligations of such *trading vehicles* or affiliated *private funds*, such exposures must be reported net with those of the *reporting fund*. If an adviser to an affiliated *private fund* separately files Form PF, such adviser to the affiliated *private fund* must exclude such exposures if they have been reported in the *reporting fund's* filing.

In completing the table, classify *borrowing and collateral received* and *lending and posted collateral* according to type (*e.g., unsecured borrowing, secured borrowing*, derivatives cleared by a *CCP*, and uncleared derivatives) and the governing legal agreement (*e.g.*, a prime brokerage or other brokerage agreement for cash margin and securities lending and borrowing, a global master repurchase agreement for *repo/reverse repo*, or an *ISDA* master agreement for *synthetic long positions, synthetic short positions*, and derivatives). Report transactions under a master securities loan agreement as other *secured borrowing*.

□ Check this box if one or more prime brokerage agreements provide for cross-margining of derivatives and secured financing transactions. If you have checked this box, and collateral does not clearly pertain to secured financing vs. derivatives transactions, report exposures and collateral as follows:

- For secured financing, exposures and collateral should be reported in sections (b), (c) and (d), as applicable
- For derivatives,
  - Report the *gross notional value* and the mark-to-market exposure of the derivatives transactions with *other derivatives* transactions (lines (e)(i) or lines (f)(i) and (ii))
  - Report associated collateral as collateral received *(B/CR)* or posted collateral *(L/PC)* under the prime brokerage agreement (lines (b)(ii) and (iii)).
- For derivatives cleared by a *CCP*, for cases where the prime broker gathers additional collateral in excess of that required by exchanges, report collateral posted by the *reporting fund* to meet exchange requirements in the cleared derivatives section on lines (e)(ii) and (iii), and any additional collateral gathered by the prime broker under a cross margining agreement should appear on lines (b) (ii) and (iii).

Consolidated Counterparty Exposure Table	***B/CR***	***L/PC***
(a) *Unsecured borrowing – cash and cash equivalents*		Not Applicable
(b) *Secured borrowing* and lending (prime brokerage or other brokerage agreement)		
(i) *cash and cash equivalents* received in cash margin borrowing, or received or paid by the *reporting fund* in securities lending and short sale transactions		
(ii) *cash and cash equivalents* received or posted by the *reporting fund* as collateral for derivatives under any cross-margining agreement		
(iii) *government securities* and other securities received and posted by the *reporting fund*		
(c) *Secured borrowing* and lending via *repo* and *reverse repo* (include tri-party repo)		
(i*) cash and cash equivalents*		
(ii) *government securities* and other securities (other than *cash and cash equivalents)* received and posted by the *reporting fund*		
(d) Other *secured borrowing* and lending (describe in Question 4)		
(i) *cash and cash equivalents*		
(ii) *government securities* and other securities (other than *cash and cash equivalents)* received and posted by the *reporting fund*		
(e) Derivative positions cleared by a *CCP*		
(i) mark-to-market exposure of derivatives transactions before collateral		
(ii) *cash and cash equivalents* received and posted by the *reporting fund* as collateral		
(iii) *government securities* and other securities received and posted by the *reporting fund* as collateral		
(f) Derivative positions that are not cleared by a *CCP* (uncleared)		
(i) *gross notional value* of *synthetic long positions* and *synthetic short positions*		
(ii) mark-to-market exposure of derivatives transactions before collateral		
(iii) *cash and cash equivalents* received and posted by the *reporting fund* as collateral		
(iv) *government securities* and other securities received and posted by the *reporting fund* as collateral		

27. Identify each creditor or other counterparty (including *CCPs*) to which the *reporting fund* owed an amount in respect of *cash borrowing entries*(before posted collateral) which is equal to or greater than either (1) 5% of *net asset value* as of the *data reporting date,* or (2) $1 billion. If there are more than five such counterparties, report the five counterparties to which the *reporting fund* owed the largest dollar amount in *cash borrowing entries* before taking into account collateral posted by the *reporting fund. (You are not required to complete this question if the reporting fund is a* qualifying hedge fund *and you complete Question 42 in Section 2).*

In the table below, report the legal entity name and *LEI* of each creditor or other counterparty, if it has

one, in columns (i) and (ii). Indicate whether the creditor or counterparty is affiliated with a major financial institution in column (iii). If you select "other," name and describe the financial institution in Question 4. Do not treat affiliated counterparty entities as a single group, except that, if the applicable contractual and legal documentation requires cross margining, report the *LEI* of the contractual counterparty, typically the prime broker.

Report the *reporting fund's cash borrowing entries* for each reported creditor or counterparty in column (iv) as a negative number. Report in column (v) the *collateral posted entries* posted by the *reporting fund* for each reported creditor or other counterparty as a positive number. Report the legal name in column (vi) and its *LEI*, if any, in column (vii), of the entity that has the counterparty exposure.

(i) Legal name of the counterparty	**(ii) Counterparty *LEI, if any***	**(iii) Indicate below if the counterparty is affiliated with a major financial institution**	***(iv) Borrowing* by *reporting fund (in U.S. dollars)***	**(v) Collateral posted by *reporting fund* (in U.S. dollars)**	**(vi) Legal name of entity**	**(vii) Entity *LEI*, if any**
(a)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(b)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(c)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(d)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(e)		[drop-down list of counterparty names] Other: _____ [Not applicable]				

28. Provide the following information for counterparties to which the *reporting fund* had net mark to market counterparty credit exposure, **after** taking into account collateral received or posted by the *reporting fund,* which is equal to or greater than either (1) 5% of the *reporting fund's net asset value* as of the *data reporting date*, or (2) $1 billion. Include *CCPs* or other third parties holding collateral posted by the *reporting fund* in respect of cleared exposures (including tri-party repo). If there are more than five such counterparties, report the five to which the *reporting fund* had the greatest mark to market exposure after taking into account collateral. *(You are not required to complete this question if the reporting fund is a* qualifying hedge fund *and you complete Question 43 in Section 2).*

For counterparties to which the *reporting fund* had net *borrowing* exposure, the *reporting fund's* net mark to market counterparty credit exposure **before** collateral equals the *reporting fund's cash borrowing entries*. The *reporting fund's* net mark to market counterparty credit exposure **after**

collateral is the amount (if any) by which the *reporting fund's collateral posted entries* exceed such *cash borrowing entries.*

For counterparties to which the *reporting fund* had net lending exposure, the *reporting fund's* net mark to market counterparty exposure **before** collateral means the *cash lending entries.* The *reporting fund's* net mark to market counterparty credit exposure **after** collateral equals the amount (if any) by which the *reporting fund's cash lending entries* exceeds the *collateral received entries.*

For all counterparties (whether the *reporting fund* had *borrowing* or lending exposure), these computations will produce a positive value for the counterparties to which the *reporting fund* had net mark to market counterparty credit exposure **after** collateral. This may occur where the *reporting fund's* posted collateral exceeded *borrowings* by the *reporting fund* from a counterparty. It also may occur where collateral received by the *reporting fund* fell short of the *reporting fund's* net mark to market counterparty credit exposure through *cash and cash equivalents* received by a counterparty in margin borrowing, securities lending, *repo* and *reverse repo* transactions, and mark to market exposure in derivatives transactions.

Report the legal entity name and *LEI* of each creditor or other counterparty, if it has one, in column (i) and (ii) below. Indicate if the counterparty is affiliated with a major financial institution in column (iii). If you select "other," name and describe the financial institution in Question 4. In columns (iv) and (v), provide the *reporting fund's* net mark to market counterparty credit exposure, **before** taking into account collateral (which will be a negative number where the *reporting fund* is a net borrower, and a positive number where the *reporting fund* is a net lender), and net mark to market counterparty credit exposure, **after** taking into account collateral (which will always be a positive number for counterparties included in this table). Report the legal name in column (vi) and its *LEI*, if any, in column (vii), of the entity that has the counterparty exposure.

Do not treat affiliated counterparty entities as a single group, except that, if the applicable contractual and legal documentation requires cross margining, report the legal entity name and *LEI* of the contractual counterparty, typically the prime broker.

(i) Legal name of the counterparty	**(ii) Counter-party *LEI, if any***	**(iii) Indicate if the counterparty is affiliated with a major financial institution**	**(iv) Net mark to market exposure before collateral (in U.S. dollars)**	**(v) Net mark to market exposure after collateral (in U.S. dollars)**	**(vi) Legal name of entity**	**(vii) Entity *LEI*, if any**
(a)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(b)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(c)		[drop-down list of counterparty names] Other: _____ [Not applicable]				
(d)		[drop-down list of counterparty names] Other: _____				

		[Not applicable]				
(e)		[drop-down list of counterparty names] Other: _____ [Not applicable]				

29. Provide the following information regarding your use of trading and clearing mechanisms during the *reporting period.*

(Provide good faith estimates of the mode in which each category was traded and cleared by the reporting fund, and not the market as a whole. For purposes of this question, a "trade" includes any transaction, whether entered into on a bilateral basis or through an exchange, trading facility or other system and whether long or short. With respect to clearing, transactions for which margin is held in a customer omnibus account at a CCP *should be considered cleared by a* CCP. *Tri-party* repo *applies where* repo/*reverse repo collateral is executed using collateral management and settlement services of a third party that does not act as a* CCP. *Sponsored* repo/reverse repo, including sponsored tri-party repo *applies to transactions in which the reporting fund has been sponsored by a sponsoring member of the Fixed Income Clearing Corporation (FICC).)*

(Enter "NA" in each part of this question for which the reporting fund engaged in no relevant trades.}

(In column (i) "value traded," report the total value *in U.S. dollars of the reporting fund's transactions in the instrument category and trading mode during the reporting period. In determining the "value traded" of derivatives trades for purposes of Questions 29(b) and 29(c), you should use the weighted-average of the notional amount of the aggregate derivatives transactions entered into by the reporting fund during the* reporting period, *except for the following: (1) for options, you would use the delta adjusted notional value, (2) for interest rate derivatives, you would use the 10-year bond equivalent.*)

(In column (ii) "end of reporting period value *of positions," report the sum of the absolute value of all of the reporting fund*'s *long and short positions in each category and mode at (a) to (d) on the last date of the* reporting period. *If you complete Section 2 for the reporting fund, the sum of the end of the* reporting period value *of positions in each category should be consistent with the sum of long and short positions for sub-asset classes in that category reported in Question 32.)*

	(i) *value* traded (in U.S. dollars)	(ii) End of reporting period *value* of positions
(a) securities (other than derivatives) that were traded by the *reporting fund.*		
On a regulated exchange		
OTC		
(b) *interest rate derivatives* that were traded by the *reporting fund*		
On a regulated exchange or swap execution facility		
OTC (and cleared by a CCP)		
*OTC/*bilaterally transacted (and not cleared by a *CCP*)		
(c) *derivatives* (other than *interest rate derivatives)* that were traded by the *reporting fund* and:		
On a regulated exchange or swap execution facility		
*OTC (*and *c*leared by a *CCP)*		
*OTC/*bilaterally transacted (and not cleared by a *CCP*)		
(d) *repo/reverse repo* trades that were entered into by the *reporting fund* and:		
Cleared by a *CCP* (other than sponsored *repo/reverse repo)*		
Cleared by a *CCP* (sponsored *repo/reverse repo).*		
Bilaterally transacted (and not cleared by a *CCP and not settled on tri-party platform*)		
Tri-party *repo/reverse repo (and not cleared by a CCP)*		

30. For transactions of the *reporting fund* that are not described in any of the categories listed in items (a) through (d) of Question 29, provide:

(a) the *value* traded (in U.S. dollars) during the *reporting period*, calculated according to the method prescribed for column (i) of Question 29, and

(b) the end of *reporting period value* of positions, calculated according to the method prescribed for column (ii) of Question 29.

Form PF Section 2	Information about *qualifying hedge fund*s that you advise

Section 2: Information about *qualifying hedge fund*s that you advise.

You must complete a separate Section 2 for each *qualifying hedge fund* that you advise, except as provided by Instruction 6. With respect to *master-feeder arrangements* and *parallel fund structures* that collectively comprise *qualifying hedge funds*, report the component funds as provided in the General Instructions. See Instructions 3, 5, and 6.

Item A. *Reporting fund* identifying information

31. (a) Name of the *reporting fund* .....

(b) *Private fund* identification number of the *reporting fund* .....

Item B. *Reporting fund* exposures and trading

32. *Reporting fund* exposures.

For each month of the *reporting period,* report the information required by (a) to (c) below for the *reporting fund's* long and short positions, by *sub-asset class* (and *instrument type,* if applicable). Report the absolute value of short positions. You are not required to report for *sub-asset classes* for which there are no relevant positions.

For this question, *sub-asset classes are: listed equity* issued by financial institutions; American Depositary Receipts; other single name *listed equity;* indices on *listed equity*; other *listed equity*; *unlisted equity* issued by financial institutions*;* other *unlisted equity; investment grade* c*orporate bonds* issued by financial institutions (other than *convertible bonds*); *investment grade* c*orporate bonds* not issued by financial institutions (other than *convertible bonds*); *non-investment grade* c*orporate bonds* issued by financial institutions (other than *convertible bonds*); *non-investment grade* c*orporate bonds* not issued by financial institutions (other than *convertible bonds*); *investment grade convertible bonds* issued by financial institutions*; investment grade convertible bonds* not issued by financial institutions*; non-investment grade convertible bonds* issued by financial institutions; non-*investment grade convertible bonds* not issued by financial institutions*;* U.S. treasury bills; U.S. treasury notes and bonds*; agency securities; GSE bonds; sovereign bonds* issued by *G10* countries other than the U.S, other *sovereign bonds* (including supranational bonds); U.S. state and local bonds; *leveraged loans;* loans (excluding *leveraged loans* and *repo);* overnight *repo,* term *repo* (other than overnight); open *repo; MBS; ABCP; CDO* (senior or higher); *CDO (*mezzanine); *CDO* (junior equity); *CLO* (senior or higher); *CLO* (mezzanine); *CLO* (junior equity); *Other ABS,* other *structured products;* U.S. dollar *interest rate derivatives;* non-U.S. currency *interest rate derivatives;* sovereign *single name CDS;* financial institution *single name CDS;* other s*ingle name CDS*; *index CDS; exotic CDS; foreign exchange derivatives; correlation derivatives; inflation derivatives; volatility derivatives; variance derivatives; other derivatives,* agricultural *commodities;* crude oil c*ommodities;* natural gas c*ommodities*; power and other energy *commodities;* gold *commodities*; other (non-gold) precious metal *commodities;* base metal commodities; *other commodities*; real estate; digital assets; U.S. currency holdings; non-U.S. currency holdings; certificates of deposit; other deposits; *money market funds*; other *cash and cash equivalents* (excluding bank deposits, certificates of deposit, *money market funds,* and U.S. treasury bills*, notes and bonds*); *investments in other sub-asset classes.* If a particular asset could be classified as both a digital asset and another asset, report the asset as the non-digital asset.

Choose the *sub-asset class* (and *instrument type,* if applicable) that describes the *sub-asset class* exposure and *instrument type* of the *reporting fund's* positions with the highest degree of precision. Include positions held in side-pockets as positions of the *reporting fund*. Include any closed out and *OTC* forward positions that have not yet expired/matured. Provide the absolute value of short positions. Report cash borrowed via *reverse repo* as the short value of *repos*. See definitions of *repo* and *reverse repo* in the Glossary.

(a) (1) Except for the *sub-asset classes* identified by (a)(2) below, report the dollar *value* of long positions and the dollar *value of* short positions in each *sub-asset class* by *instrument type:* For this purpose, *instrument types* are*:* cash/physical instruments, futures, forwards, swaps, listed options, unlisted options, *other derivative* products, *ETFs,* other *exchange traded products,* U.S. registered investment companies (excluding *ETFs* and *money market funds), investments in non-U.S. registered investment companies, internal private funds, external private funds, commodity pools,* and any other company, fund or entity. For *foreign exchange derivatives,* report foreign exchange swaps and currency swaps separately. In determining dollar *value*, do not net long and short positions within *sub-asset classes* or *instrument types* (with the exception of spot foreign exchange longs and shorts).

In determining the *reporting fund's* exposure to *sub-asset classes* for positions held indirectly through entities, *e.g.*, *ETFs,* other *exchange traded products,* U.S. registered investment companies (excluding *ETFs* and *money market funds*), *investments in non-U.S. registered investment companies, external private funds, internal private funds, commodity pools*, or other companies, funds or entities, you may allocate the position among *sub—asset classes* and *instrument types* using reasonable estimates consistent with your internal methodologies and conventions of service providers. You may report an entirely indirectly held entity position in one sub-asset class and *instrument type* that best represents the *sub-asset class* exposure of the indirectly held entity, unless you would allocate the exposure of the indirectly held entity more granularly under your own internal methodologies and conventions of your service providers.

(i) Long:
(ii) Short:

(2) Report the dollar *value* of long positions and the dollar value of short positions for the *sub-asset class* (not by *instrument type*) for these *sub-asset classes*: *leveraged loans,* loans (excluding *leveraged loans* and *repo);* overnight *repo,* term *repo* (other than overnight), open *repos;* sovereign *single name CDS;* financial institution *single name CDS;* other s*ingle name CDS*, *index CDS; exotic CDS;* U.S. currency holdings, non-U.S. currency holdings, certificates of deposit, other deposits, *money market funds,* other *cash and cash equivalents* (excluding bank deposits, certificates of deposit, *money market funds,* and U.S. treasury bills, notes and bonds).

(i) Long:
(ii) Short:

Describe the nature of the *reporting fund's* investment positions in Question 4, if you report long or short dollar *value* equal to or exceeding either (1) 5% of the *reporting fund's net asset value* or (2) $1 billion in any of these *sub-asset classes:* loans (excluding *leveraged loans* and *repo*), other *structured products, other derivatives*, *other commodities,* digital assets, *investments in other sub-asset classes*.)

(b) *Adjusted exposure* (1) For each *sub-asset class* in which the *reporting fund* held relevant positions, calculate the *adjusted exposure* of long and short positions by netting positions in the same underlying *reference asset* across *instrument type*, and for fixed income assets, within the same term, using the following *maturity* buckets: 0-1 year, 1-2 year, 2-5 year, 5-10 year, 10-15 year, 15-20 year, and 20+ year. You may net counterparties consistent with the information you report internally and to current and prospective investors.

(i) Long:
(ii) Short:

(2) If, under your methodologies for internal reporting and reporting to investors, you do not net all positions across all *instrument types* in monitoring the economic exposure of the *reporting fund's* investment positions, you must also (i) report *adjusted exposure* for each *sub-asset class* calculated using your internal methodologies, and (ii) describe in Question 4 how

your internal methodologies differ from the calculations required by subsection (b)(1).

(c) Interest rate risk (*10-year bond equivalent)*. For *sub-asset classes* with interest rate risk, report the *10-year bond equivalent* of the *sub-asset class* long position dollar *value* and short position dollar *value* (by *instrument* type, if applicable) and *adjusted exposure*. Report *10-year bond equivalent* as a long value for positions that have a gain when rates decline, and as a short value for positions that have a loss when rates decline,

(NOTE: *10-year bond equivalent* is required for these *sub-asset classes: investment grade* c*orporate bonds* issued by financial institutions (other than *convertible bonds*); *investment grade* c*orporate bonds* not issued by *financial institutions* (other than *convertible bonds*); *non-investment grade* c*orporate bonds* issued by financial institutions (other than *convertible bonds*); *non-investment grade* c*orporate bonds* not issued by *financial institutions* (other than *convertible bonds*); *investment grade convertible bonds* issued by *financial institutions; investment grade convertible bonds* not issued by financial institutions*; non-investment grade convertible bonds* issued by *financial institutions;* non-*investment grade convertible bonds* not issued by financial institutions*;* U.S. treasury bills, U.S. treasury notes and bonds; *U.S. agency securities; GSE bonds; sovereign bonds* issued by *G10* countries other than the U.S, other *sovereign bonds* (including supranational bonds); U.S. state and local bonds; *leveraged loans,* loans (excluding *leveraged loans* and *repo*)*;* overnight *repo,* term *repo* (other than overnight), open *repo, MBS, ABCP,* Senior or higher *CDO,* Mezzanine *CDO,* Junior equity *CDO,* Senior or higher *CLO,* Mezzanine *CLO,* Junior equity *CLO, Other ABS, other structured products;* U.S. dollar *interest rate derivatives*, non-U.S. currency *interest rate derivatives;* certificates of deposit).

33. (a) For each month of the *reporting period,* report the net long value and net short value of the *reporting fund's* currency exposure arising from *foreign exchange derivatives* and all other assets and liabilities of the *reporting fund* that are denominated in a currency other than the *reporting fund's* base currency.

Currency	1st Month		2nd Month		3rd Month	
	Long value	Short value	Long value	Short value	Long value	Short value
[drop-down of currencies]						
[drop-down of currencies]						

(b) For each month of the *reporting period,* identify each currency to which the *reporting fund* has long dollar *value* or short dollar *value* exposure equal to or exceeding either (1) 5% of the *reporting fund's net asset value* or (2) $1 billion and report the long dollar *value* and short dollar *value* of this exposure in U.S. dollars.

In responding to this question, include the spot currency exposure arising from all holdings, including assets denominated in foreign currencies, and derivative products with currency exposure. Include currency exposure obtained indirectly (e.g., through ETFs, exchange traded products, U.S. registered investment companies, non-U.S. registered investment companies, internal private funds, external private funds, commodity pools, or other companies, funds or entities). You may report reasonable estimates, if consistent with your internal methodologies and conventions of service providers. For indirectly held exposures, report currency exposures using reasonable estimates that best represent the exposures of the entity and are consistent with your internal methodologies and conventions of service providers.

Currency	1st Month		2nd Month		3rd Month	
	Long value	Short value	Long value	Short value	Long value	Short value
[drop-down of currencies]						
[drop-down of currencies]						

34. For each month of the *reporting period*, provide the *value* of turnover during the month in each of the asset classes listed below for the *reporting fund*.

(The value *of turnover is the sum of the absolute* values *of transactions in the relevant asset class*

during the period.).

	1st Month	2nd Month	3rd Month
*Listed equity (*exclude *listed equity derivatives)*.....			
Corporate bonds (other than *convertible bonds;* exclude derivative exposure to *corporate bonds*)....			
*Convertible bonds (*exclude derivative exposure to *convertible bonds)*.....			
Sovereign bonds and municipal bonds (exclude derivative exposure)			
U.S. treasury bills.....			
U.S. treasury notes and bonds.....			
Agency securities …….			
GSE bonds.....			
Sovereign bonds issued by *G10* countries other than the U.S.....			
Other *sovereign bonds* (including supranational bonds).....			
U.S state and local bonds.....			
Listed equity derivatives…….			
Interest rate derivatives…….			
U.S. dollars.....			
Futures……..			
Swaps……..			
Options…….			
Other derivative instrument types			
Non-U.S. currencies			
Futures.....			
Swaps.....			
Options.....			
Other derivative instrument types			
Foreign Exchange Derivatives …….			
Swaps…….			
Options …….			
Other instrument types …….			
Derivative exposure to U.S treasury securities…….			
Derivative exposure to sovereign bonds issued by G10 countries other than the U.S....			
Derivative exposure to other sovereign bonds.....			
Other derivatives…….			

35. For each month of the *reporting period,* identify by ISO country code, each country to which the *reporting fund* has long dollar *value* or short dollar *value* exposure equal or exceeding either (1) 5% of the *reporting fund's net asset value* or (2) $1 billion., and report the long dollar *value* and short dollar *value* of this exposure in U.S. dollars.

(See Instruction 15 for information on calculating the numerator for purposes of this Question. Categorize investments based on concentrations of risk and economic exposures, and include country exposure obtained indirectly (e.g., through ETFs, exchange traded products, U.S. registered investment companies, non-U.S. registered investment companies, internal private funds, external private funds, commodity pools, or other companies, funds or entities. You may report reasonable estimates, if consistent with your internal methodologies and conventions of service providers. For indirectly held exposures, report country exposures using reasonable estimates that best represent the exposures of the entity and are consistent with your internal methodologies and conventions of service providers.

ISO Code	1st Month		2nd Month		3rd Month	
	Long value	Short value	Long value	Short value	Long value	Short value
[drop-down of ISO Code]						
[drop-down of ISO Code]						

36. For each month of the *reporting period,* identify the *reporting fund's* exposure by industry, based on the *NAICS codes* of the underlying exposures, equal or exceeding either: (1) 5% of the *reporting fund's net asset value* or (2) $1 billion, and report the long dollar *value* and short dollar *value* of this exposure in U.S. dollars.

Include industry exposure obtained indirectly (*e.g.*, through *ETFs, exchange traded products,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private funds, external private funds, commodity pools,* or other companies, funds or entities). *You may respond to this Question using reasonable estimates based on your internal methodologies consistent with information you report internally and to investors. For indirectly held exposures, report industry exposures using reasonable estimates that best represent the exposures of the entity and are consistent with your internal methodologies and conventions of service providers.*

NAICS Code	1st Month		2nd Month		3rd Month	
	Long value	Short value	Long value	Short value	Long value	Short value
[drop-down of *NAICS Code*]						
[drop-down of *NAICS Code*]						

37. Provide the following information regarding the liquidity of the *reporting fund's* portfolio.

Specify the percentage by value of the *reporting fund*'s positions that may be liquidated within each of the periods specified below. Each investment can be assigned to more than one period, but assignments should be based on the shortest period during which you believe that such position could reasonably be liquidated at or near its carrying value. If an investment is assigned to more than one period, reflect the percentage of *net asset value* that might be liquidated within each period (as opposed to the percentage of *net asset value* that the entire investment represents). Use good faith estimates for liquidity based on market conditions over the reporting period and assuming no fire-sale discounting. Estimates must be based on a methodology that takes into account changes in portfolio composition, position size and market conditions over time. For example, estimates would change if the portfolio invests in more or less liquid assets, if/when the portfolio investments grow to a size relatively to the liquidity of the markets in which it invests that requires more time to liquidate, and if liquidity characteristics change measurably and meaningfully for the assets in which the portfolio invests. In the event that individual positions are important contingent parts of the same trade, group all those positions under the liquidity period of the least liquid part (so, for example, in a *convertible bond* arbitrage trade, the liquidity of the short should be the same as the *convertible bond*). Include *cash and cash equivalents*.

(The total should add up to approximately 100%.)

	% of NAV
1 day or less	
2 days – 7 days	
8 days – 30 days	
31 days – 90 days	
91 days – 180 days	
181 days – 365 days	
Longer than 365 days	

38. *Value* of *reporting fund's unencumbered cash*.....

1st Month	2nd Month	3rd Month

39. Report the following with respect to the *reporting fund*'s long and short *netted exposure* to *reference assets* at the end of each month of the *reporting period:*

For purposes of this Question 39, *netted exposure* means the sum of all positions with legal and contractual rights that provide exposure to the same *reference asset.* Take into account all positions, including offsetting and partially offsetting positions, relating to the same *reference asset* (without regard to counterparties or issuers of a derivative or other instrument that reflects the price of the *reference asset*). The *netted exposure* to a *reference asset* will be either long or short. Determine the value of each *netted exposure* to each *reference asset* in U.S. dollars, expressed as the delta adjusted notional value, or as the *10-year bond equivalent* for *reference assets* that are fixed income assets.

Do not report exposure to *cash and cash equivalents.*

.

	1st Month		2nd Month		3rd Month	
	Long	*Short*	*Long*	*Short*	*Long*	*Short*
(a) Total number of *reference assets* to which the *reporting fund* holds long and short *netted exposure* (approximate)						
(b) Percent of *net asset value* represented by the aggregated *netted exposures* of *reference assets* with the top five (5) long and short *netted exposures*.						
(c) Percent of *net asset value* represented by the aggregate *netted exposures* of *reference assets* representing the top ten (10) long and short *netted exposures*.						

40. As of the end of each month in the *reporting period,* provide the information requested below for each *reference asset* to which the *reporting fund* has *gross exposure* equal to or exceeding:

(i) 1% of *net asset value*, if the *reference asset* is a debt security and the *reporting fund's gross exposure* to the *reference asset* exceeds 20% of the size of the overall debt security issuance;
(ii) 1% of *net asset value,* if the *reference asset* is a *listed equity* and the *reporting fund's gross exposure* to the *reference asset* exceeds 20% of average daily trading volume measured over 90 days preceding the reporting date; or
(iii) either (1) 5% of the *reporting fund's net asset value* or (2) $1 billion.

For purpose of this Question 40, the *reporting fund's gross exposure* to a *reference asset* means the sum of the absolute value of all long and short positions with legal and contractual rights that provide exposure to the *reference asset*.

(a) First month of the *reporting period,* Position 1, 2, 3, etc.
- (i) Dollar *value* (in U.S. dollars) of all long positions with legal and contractual rights that provide exposure to the *reference asset*.
- (ii) Dollar *value* (in U.S. dollars) of all short positions with legal and contractual rights that provide exposure to the *reference asset*.
- (iii) *Netted exposure* to *reference asset* (as defined by Question 39 Instructions).
- (iv) *Sub-asset class and instrument type:* Instruction: *Select all that apply.* [two drop down menus]
- (v) Title or description of *reference asset*:
- (vi) *Reference asset* issuer (if any) name and *LEI.*
- (vii) CUSIP (if any), and at least one of the following other identifiers: (i) ISIN; (ii) Ticker if ISIN is not available); (iii) Other unique identifier (if ticker and ISIN are not available) [Must indicate type of identifier used].
- (viii) For *reference assets* with no CUSIP or other identifier, describe the *reference asset.*
- (ix) If the *reference asset* is a debt security, size of issue:
- (x) If the *reference asset* is a *listed equity*, average daily trading volume, measured over 90 days preceding the *reporting date.*
- (xi) FIGI (optional)

(b) Second month of the *reporting period,* Position 1, 2, 3, etc. (same list of information to collect)

(c) Third month of the *reporting period,* Position 1, 2, 3, etc. (same list of information to collect)

41. *Consolidated Counterparty Exposure Table*

Report in the *consolidated counterparty exposure table* below the *reporting fund's borrowing and collateral received (B/CR)* and *lending and posted collateral (L/PC)* aggregated across all counterparties (including all *CCPs*) in U.S. dollars as of the end of each month of the *reporting period*.

You must net the *reporting fund's* exposure with each counterparty and among affiliated entities of a counterparty to the extent such exposures may be contractually or legally set-off or netted across those entities and/or one *affiliate* guarantees or may otherwise be obligated to satisfy the obligations of another under the agreements governing the transactions. Netting must be used to reflect net cash borrowed from or lent to a counterparty, but must not be used to offset securities borrowed and lent against one another, when reporting prime brokerage and *repo/reverse repo* transactions.
Classify *borrowing* by creditor type (*e.g.*, percentage borrowed from *U.S. depository institutions,* U.S. creditors that are not *U.S depository institutions,* non-U.S. creditors) based on the legal entity that is the contractual counterparty for such borrowing and not based on parent company or other affiliated group.

Report the counterparty exposures of *trading vehicles* owned by the *reporting fund* based on the *reporting fund*'s percentage ownership of each *trading vehicle*, without netting these exposures with those of the *reporting fund* if they are not guaranteed by the *reporting fund* or contractual obligations of the *reporting fund*. If the *reporting fund* guarantees or is contractually obligated to fulfill

obligations of such *trading vehicles* or affiliated *private funds*, such exposures must be reported net with those of the *reporting fund*. If an adviser to an affiliated *private fund* separately files Form PF, such adviser must exclude such exposures if they have been included in the *reporting fund*'s filing.

In completing the table, classify *borrowing and collateral received* and *lending and posted collateral* according to type, (*e.g.*, *unsecured, secured borrowing,* derivatives cleared by a *CCP,* and uncleared derivatives) and the governing legal agreement, *e.g.*, a prime brokerage or other brokerage agreement for cash margin and securities lending and borrowing, a global master repurchase agreement for *repo/reverse repo*, or an *ISDA* master agreement for *synthetic long positions, synthetic short positions* and *other derivatives*. Report transactions under master securities loan agreement as other *secured borrowing*.

□ Check this box if one or more prime brokerage agreements provide for cross-margining of derivatives and secured financing transactions. If you have checked this box, and collateral does not clearly pertain to secured financing vs. derivatives transactions, report exposures and collateral as follows:

- For secured financing, exposures and collateral should be reported in sections (b), (c) and (d) as applicable.

- For derivatives,
  - Report the *gross notional value* and the mark-to-market of the derivatives transactions with *other derivatives* transactions (line (e)(i) or lines (f)(i) and (ii)
  - Report associated collateral as collateral received *(B/CR)* or posted collateral *(L/PC)* under the prime brokerage agreement (lines (b)(ii),(iii), (iv) and (v)).
- For derivatives cleared by a *CCP*, for cases where the prime broker gathers additional collateral in excess of that required by exchanges, report collateral posted by the *reporting fund* to meet exchange requirements in the cleared derivatives section on lines (e)(ii), (iii), (iv), and (v) and any additional collateral gathered by the prime broker under a cross margining agreement should appear on lines (b)(ii), (iii),(iv) and (v).

	1st Month		2nd Month		3rd Month	
	B/CR	***L/PC***	***B/CR***	***L/PC***	***B/CR***	***L/PC***
(a) *Unsecured borrowing – cash and cash equivalents*		Not Applicable		Not Applicable		Not Applicable
(A) percentage borrowed from *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(B) percentage borrowed from U.S. creditors that are not *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(C) percentage borrowed from non-U.S. creditors		Not Applicable		Not Applicable		Not Applicable
(b) *Secured borrowing* and lending (prime brokerage or other brokerage agreement)						
(i) *cash and cash equivalents* received in cash margin borrowing, or received or paid by the *reporting fund* in securities lending and short sale transactions						
(ii) *cash and cash equivalents* received and posted by the *reporting fund* as collateral for derivatives under any cross-margining agreement						
(iii) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund*						
(iv) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund*						

	1st Month		2nd Month		3rd Month	
	B/CR	***L/PC***	***B/CR***	***L/PC***	***B/CR***	***L/PC***
(v) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*						
(vi) percentage of *secured borrowing* (prime brokerage or other brokerage agreement) (sum of (b)(i), (iii), (iv) and (v))						
(A) borrowed from *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(B) borrowed from U.S. creditors that are not *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(C) borrowed from non-U.S. creditors		Not Applicable		Not Applicable		Not Applicable
(vii) at the end of each month of the *reporting period*, expected increase in collateral required to be posted by the *reporting fund,* if required margin increases by 1% of position size.	Not Applicable		Not Applicable		Not Applicable	

(c) *Secured borrowing* and lending via *repo* and *reverse repo* (include tri-party repo)

(i*) cash and cash equivalents*						
(ii) *government securities* (other than *cash and cash equivalents)* received and posted by the *reporting fund*						
(iii) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund*						
(iv) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*						
(v) percentage of *secured borrowing* via *repo* and *reverse repo* (sum of (c)(i), (ii), (iii) and (iv))						
(A) borrowed from *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(B) borrowed from U.S. creditors that are not *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(C) borrowed from non-U.S. creditors		Not Applicable		Not Applicable		Not Applicable
(vi) at the end of each month of the *reporting period*, expected increase in collateral required to be posted by the *reporting fund,* if required margin increases by 1%	Not Applicable		Not Applicable		Not Applicable	

(d) Other *secured borrowing* and lending (describe in Question 4)

(i) *cash and cash equivalents*						
(ii) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund*						
(iii) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund*						
(iv) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*						
(v) percentage of other *secured borrowing* (sum of (d)(i), (ii), (iii) and (iv))						
(A) borrowed from *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(B) borrowed from U.S. creditors that are not *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(C) borrowed from non-U.S. creditors		Not Applicable		Not Applicable		Not Applicable

	1st Month		2nd Month		3rd Month	
	B/CR	*L/PC*	*B/CR*	*L/PC*	*B/CR*	*L/PC*
(vi) at the end of each month of the *reporting period*, expected increase in collateral required to be posted by the *reporting fund,* if required margin increases by 1%	Not Applicable		Not Applicable		Not Applicable	

(e) Derivative positions cleared by a *CCP*

(i) mark-to-market exposure of derivatives transactions before collateral						
(ii) *cash and cash equivalents* received and posted by the *reporting fund* as collateral						
(iii) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund* as collateral						
(iv) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund* as collateral						
(v) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*						
(vi) at the end of each month of the *reporting period*, expected increase in collateral required to be posted by the *reporting fund,* if required margin increases by 1%	Not Applicable		Not Applicable		Not Applicable	

(f) Derivative positions that are not cleared by a *CCP* (uncleared)

(i) *gross notional value* of *synthetic long positions* and *synthetic short positions*						
(ii) mark-to-market exposure of derivatives transactions before collateral						
(iii) *cash and cash equivalents* received and posted by the *reporting fund* as collateral						
(iv) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund* as collateral						
(v) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund* as collateral						
(vi) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*						
(vii) percentage of *synthetic long positions* (sum of (f)(i), (iii), (iv) and (v))						
(A) from *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(B) from U.S. creditors that are not *U.S. depository institutions*		Not Applicable		Not Applicable		Not Applicable
(C) from non-U.S. creditors		Not Applicable		Not Applicable		Not Applicable
(viii) at the end of each month of the *reporting period*, expected increase in collateral required to be posted by the *reporting fund,* if required margin increases by 1%	Not Applicable		Not Applicable		Not Applicable	

42. Identify each creditor or other counterparty (including *CCPs*) to which the *reporting fund* owed an amount in respect of *cash borrowing entries* (before posted collateral) which is equal to or greater than either (1) 5% of *net asset value* as of the *data reporting date,* or (2) $1 billion. In subsection (a), complete an *individual counterparty exposure table* for the five creditors and counterparties to which the *reporting fund* owed the greatest dollar amount in *cash borrowing entries* (before posted collateral). Follow the instructions for the *consolidated counterparty exposure table* in completing each *individual counterparty exposure table*.

Identify in subsection (b) all other creditors and counterparties (including *CCPs*) that were not the top five listed in the *individual counterparty exposure tables,* but to which the *reporting fund* owed an amount in respect of *cash borrowing entries* (before posted collateral) which is equal to or greater than either (1) 5% of the *reporting fund's net asset value* as of the *data reporting date*, or (2) $1 billion.

For the entities identified in subsection (b), report the legal entity name and *LEI* of each creditor or other counterparty, if it has one, as indicated in subsections (a)(i) or in subsection (b) at columns *(a)* and *(c)*. Indicate whether the creditor or counterparty is affiliated with a major financial institution in subsection (a)(i)*(c)* or in subsection (b) at column *(c)*. If you select "other," name and describe the financial institution in Question 4. You may not treat affiliated counterparty entities as a single group, except that, if the applicable contractual and legal documentation requires cross margining, report the *LEI* of the contractual counterparty, typically the prime broker.

For subsection (b), for each entity identified, report the *cash borrowing entries* as determined above in column *(d)* as a negative number and report total *collateral posted entries* by the *reporting fund* in column *(e)* as a positive number. Report the legal name in column (vi) and its *LEI*, if any, in column (vii), of the entity that has the counterparty exposure.

(a) *Individual Counterparty Exposure Table* - Top 5 Creditor Counterparties [1, 2, 3, 4, 5]: *(Because* borrowing *and cash lending should be netted for each counterparty, only one entry is required in each row of this table.)*

(i) *(a)* Legal name of counterparty,
(b) Counterparty *LEI*, if any,
(c) indicate if affiliated with a major financial institution [drop-down menu],
(d) Borrowing by the *reporting fund*,
(e) Collateral posted by the *reporting fund*,
(f) Legal name of entity that has the exposure, and
(g) Entity *LEI*, if any

	B/CR	***L/PC***
(ii) *Unsecured borrowing – cash and cash equivalents*		NA

	B/CR	L/PC

(iii) *Secured borrowing* and lending (prime brokerage or other brokerage agreement

□ Check this box if one or more prime brokerage agreements provide for cross-margining of derivatives and secured financing transactions. If you have checked this box, and collateral does not clearly pertain to secured financing vs. derivatives transactions, report exposures and collateral as follows:

- For secured financing, exposures and collateral should be reported in sections (iii), (iv) and (v), as applicable
- For derivatives,
  - Report the *gross notional value* and the mark-to-market of the derivatives transactions with *other derivatives* transactions (lines (vi)(A) and (vii)(A) and (B))
  - Report associated collateral as collateral received (*B/CR*) or posted collateral (*L/PC*) under the prime brokerage agreement (lines (iii)(B),(C), (D) and (E)).
- For derivatives cleared by a *CCP*, for cases where the prime broker gathers additional collateral in excess of that required by exchanges, report collateral posted by the *reporting fund* to meet exchange requirements in the cleared derivatives section on lines (vi)(B), (C), (D), and (E), and enter any additional collateral gathered by the prime broker under a cross margining agreement on lines (iii)(B),(C), (D) and (E).

(A) *cash and cash equivalents* received in cash margin borrowing, or received or paid by the *reporting fund* in securities lending and short sale transactions		
(B) *cash and cash equivalents* received and posted by the *reporting fund* as collateral for derivatives under any cross-margining agreement		
(C) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund*		
(D) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund*		
(E) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*		

(iv) *Secured borrowing* and lending via *repo* and *reverse repo* (include tri-party repo

(A*) cash and cash equivalents*		
(B) *government securities* (other than *cash and cash equivalents)* received and posted by the *reporting fund*		
(C) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund*		
(D) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*		

(v) Other *secured borrowing* and lending (describe in Question 4)

(A) *cash and cash equivalents*		
(B) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund*		

	B/CR	L/PC
(C) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund*		
(D) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*		

(vi) Derivative positions cleared by a *CCP*

(A) mark-to-market exposure of derivatives transactions before collateral		
(B) *cash and cash equivalents* received and posted by the *reporting fund* as collateral		
(C) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund* as collateral		
(D) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund* as collateral		
(E) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*		

(vii) Derivative positions that are not cleared by a *CCP* (uncleared)

(A) *gross notional value* of *synthetic long positions* and *synthetic short positions*		
(B) mark-to-market exposure of derivatives transactions before collateral		
(C) *cash and cash equivalents* received and posted by the *reporting fund* as collateral		
(D) *government securities* (other than *cash and cash equivalents*) received and posted by the *reporting fund* as collateral		
(E) securities (other than *cash and cash equivalents* and *government securities)* received and posted by the *reporting fund* as collateral		
(F) other collateral or credit support (including face amount of letters of credit and similar third party credit support) received and posted by the *reporting fund*		

(b) Other Creditors and Counterparties

(a) Legal name of creditor or other counterparty	*(b)* Counterparty *LEI*, if any	*(c)* Indicate if creditor or other counterparty is affiliated with a major financial institution	*(d) Borrowing* by the *reporting fund* (in U.S. dollars)	*(e)* Collateral posted by the *reporting fund* (in U.S. dollars)	(f) Entity Legal Name	(g) Entity *LEI*, if any
(i)		[drop-down list of counterparty names] Other: [Not applicable]				
(ii)		[drop-down list of counterparty names] Other: [Not applicable]				
(iii)		[drop-down list of counterparty names] Other: [Not applicable]				

43. Provide the information required by this question for counterparties to which the *reporting fund* had net

mark to market counterparty credit exposure, **after** taking into account collateral received or posted by the *reporting fund,* which is equal to or greater than either (1) 5% of the *reporting fund's net asset value* as of the *data reporting date,* or (2) $1 billion. Include *CCPs* or other third parties holding posted collateral of the *reporting fund* in respect of cleared exposures (including tri-party *repo*).

For counterparties to which the *reporting fund* had net *borrowing* exposure,

the *reporting fund's* net mark to market counterparty credit exposure **before** collateral equals the *reporting fund's cash borrowing entries.* The *reporting fund's* net mark to market counterparty credit exposure **after** collateral is the amount (if any) by which the *collateral posted entries* exceed such *cash borrowing entries.*

For counterparties to which the *reporting fund* had net lending exposure, the *reporting fund's* net mark to market counterparty credit exposure **before** collateral means the *cash lending entries.* The *reporting fund's* net mark to market counterparty credit exposure **after** collateral equals the amount (if any) by which the *reporting fund's cash lending entries* exceed the *collateral received entries*.

For all counterparties (whether the *reporting fund* had borrowing or lending exposure), these computations will produce a positive value for the counterparties to which the *reporting fund* had net mark to market counterparty credit exposure **after** collateral. This may occur where the *reporting fund's* posted collateral exceeded *borrowings* by the *reporting fund* from a counterparty. It also may occur where collateral received by the *reporting fund* fell short of the *reporting fund's* net mark to market counterparty credit exposure through *cash and cash equivalents* received by a counterparty in margin borrowing, securities lending, *repo* and *reverse repo* transactions, and mark to market exposure in derivatives transactions.

Provide the information required by the *individual counterparty exposure table at* subsection (a) for the five counterparties to which the *reporting fund* had the greatest dollar net mark to market counterparty credit exposure **after** collateral. Do not report any counterparties that are reported in above in Question 42(a)) and do not include counterparties to which the *reporting fund's* net market to market counterparty exposure (after collateral) was not greater than either (1) 5% of the *reporting fund's net asset value* on the *data reporting date*, or (2) $1 billion.

If there are more than five counterparties to which the *reporting fund* had net mark to market counterparty credit exposure **after** collateral which was equal to or greater than either (1) 5% of the *reporting fund's net asset value* as of the *data reporting date*, or (2) $1 billion (and which are not reported in Question 42(a)), identify these additional counterparties in subsection (b). Report, for each such counterparty, the *reporting fund's* net mark to market counterparty credit exposure, **before** taking into account collateral (column *(d)*) which will be a negative number where the *reporting fund* is a net borrower, and a positive number where the *reporting fund* is a net lender, and net mark to market counterparty credit exposure, **after** taking into account collateral (column *(e)*), which will always be a positive number for any counterparties included in this table.

In the *individual counterparty exposure table*, report the legal entity name and *LEI* of each creditor or other counterparty, if it has one, as indicated in subsection (a)(i)*(a)* and (a) (i)*(b)* or in subsection (b), columns *(a)* and *(b)*. Indicate in subsection (a)(i)*(c)* or subsection (b), column *(c),* if the counterparty is affiliated with a major financial institution. If you select "other," name and describe the financial institution in Question 4. Report the legal entity name and *LEI*, if any, of each entity that has the counterparty exposure in columns (f) and (g). You may not treat affiliated counterparty entities as a single group, except that, if the applicable contractual and legal documentation requires cross margining, report the legal entity name and *LEI* of the contractual counterparty, typically the prime broker.

43(a) *Individual Counterparty Exposure Table* — Top "Debtor" Counterparties *Complete the Individual Counterparty Exposure Table (see Q42(a)) for each of the top "debtor" counterparties)*

43(b) Other Counterparties

(a) Legal name of counterparty	*(b)* Counterparty *LEI,* if any	*(c)* Indicate if counterparty is affiliated with a major financial institution	*(d)* Net mark to market exposure before collateral (in U.S. dollars)	*(e)* Net mark to market exposure after collateral (in U.S. dollars)	(f) Legal name of entity	(g) Entity *LEI*, if any
(i)		[drop-down list of counterparty names] Other: [Not applicable]				
(ii)		[drop-down list of counterparty names] Other: [Not applicable]				
(iii)		[drop-down list of counterparty names] Other: [Not applicable]				

44. Identify each *CCP* or other third party holding collateral posted by the *reporting fund* in respect of cleared exposures (including tri-party repo) equal to or exceeding either (1) 5% of the *reporting fund's net asset value* as of the *data reporting date* or (2) $1 billion. *(Exclude counterparties reported in Questions 42 and 43)*. If a different legal entity than the *reporting fund* owns the collateral, report the entity's legal name and its *LEI*, if any.

***CCP* or Third party legal name**	***LEI*, if any**	***CCP*/third party affiliation with a major financial institution (if any)**	**Posted Margin (in U.S. dollars)**	**Net Exposure (in U.S. dollars)**	**Legal name of entity**	**Entity *LEI*, if any**
(a)		[drop-down list of counterparty names] Other: [Not applicable]				
(b)		[drop-down list of counterparty names] Other: [Not applicable]				
(c)		[drop-down list of counterparty names] Other: [Not applicable]				

45. (a) Of the total amount of collateral and other credit support that counterparties have posted to the *reporting fund*, what percentage:

(i) may be rehypothecated?

(ii) has the *reporting fund* rehypothecated?

Item C. *Reporting fund* risk metrics and performance

46. (a) During the *reporting period*, did you regularly calculate the *VaR* of the *reporting fund*?

(Please respond without regard to whether you reported the result of this calculation internally or to investors.)

☐ Yes ☐ No

(b) If you responded "yes" to Question 46(a), provide the following information.

(If you regularly calculate the VaR of the reporting fund using multiple combinations of confidence interval, horizon and historical observation period, complete a separate response to this Question 46(b) for each such combination.)

(i) Confidence interval used (e.g., 100%-alpha%) *(as a percentage)* .....

(ii) Time horizon used *(in number of days)*.....

(iii) What weighting method was used to calculate *VaR*?

☐None ☐ Exponential ☐ Other:

(iv) If you responded "exponential" to Question 46(b)(iii), provide the weighting factor used *(as a decimal to two places)*.....

(v) What method was used to calculate *VaR*?

☐ Historical simulation ☐ Monte Carlo simulation

☐ Parametric ☐ Other:

(vi) Historical lookback period used *(in number of years; enter "NA" if none used)*.....

(vii) *VaR* at the end of the 1st month of the *reporting period (as a % of NAV)* .....

(viii) *VaR* at the end of the 2nd month of the *reporting period (as a % of NAV)* .....

(ix) *VaR* at the end of the 3rd month of the *reporting period (as a % of NAV)* .....

47. For each of the market factors identified below, determine the effect of the specified changes on the *reporting fund's* portfolio and provide the results. For market factors that have no direct effect on the *reporting fund*'s portfolio, enter zero.

In determining the *reporting fund's* exposure to changes in market factors for positions held indirectly through entities, *e.g.*, *ETFs,* other *exchange traded products,* U.S. registered investment companies (excluding *ETFs* and *money market funds*), *investments in non-U.S. registered investment companies, external private funds, internal private funds, commodity pools*, or other companies, funds or entities, you may use reasonable estimates that best represent the exposure, consistent with your internal methodologies and conventions of service providers.

(For market factors involving interest rates and credit spreads, separate the effect on your portfolio into long and short components where (i) the long component represents the aggregate result of all positions whose valuation changes in the opposite direction from the market factor under a given stress scenario, and (ii) the short component represents the aggregate result of all positions whose valuation changes in the same direction as the market factor under a given stress scenario.) (For market factors other than interest rates and credit spreads, separate the effect on your portfolio into long and short components where (i) the long component represents the aggregate result of all positions whose valuation changes in the same direction as the market factor under a given stress

scenario and (ii) the short component represents the aggregate result of all positions whose valuation changes in the opposite direction from the market factor under a given stress scenario.)

(Assume that changes in a market factor occur instantaneously and that all other factors are held constant. If the specified change in any market factor would make that factor less than zero, use zero instead.)

(Please note the following regarding the market factors identified below:

(i) A change in "equity prices" means that the prices of all equities move up or down by the specified amount, without regard to whether the equities are listed on any exchange or included in any index;

(ii) "Risk free interest rates" means rates of interest accruing on sovereign bonds *issued by governments having the highest credit quality, such as U.S. treasury securities; and interest rate swap rates in which a fixed rate is exchanged for a risk-free floating rate such as the secured overnight financing rate (SOFR) or the sterling overnight index average (SONIA);*

(iii) "Non-parallel risk free interest rate movements" means only risk free interest rates in the indicated segment of the yield curve move, and no other rates, factors or prices move, and that all rates within the indicated segment of the yield curve move by the same amount. The sum of all reported non-parallel risk free interest rate sensitivities for a given rate movement should total to the portfolio's sensitivity to a parallel risk free interest rate movement of that magnitude;

(iv) A change in "credit spreads" means that all spreads against risk free interest rates change by the specified amount;

(v) A change in "currency rates" means that the values of all currencies move up or down by the specified amount relative to the reporting fund's base currency*;*

(vi) A change in "commodity prices" means that the prices of all physical commodities move up or down by the specified amount;

(vii) A change in "option implied volatilities" means that the implied volatilities of all the options that the reporting fund holds increase or decrease by the specified number of percentage points (additive, not multiplicative); and

(viii) A change in "default rates" means that the rate at which debtors default on all instruments of the specified type increases or decreases by the specified number of percentage points.)

Not relevant	**Relevant/not formally tested**	**Market factor – changes in market factor**	**Effect on long components of portfolio (as % of *NAV*)**	**Effect on short components of portfolio (as % of *NAV*)**
☐	☐	Equity prices:		
		Equity prices increase 10%		
		Equity prices decrease 10%		
☐	☐	Non-parallel risk free interest rate movements:		
		0-3 year rates only increase 50 *bp*		
		0-3 year rates only decrease 50 *bp*		
		>3-10 year rates only increase 50 *bp*		
		>3-10 year rates only decrease 50 *bp*		
		Only all >10 year rates increase 50 *bp*		

		Only all >10 year rates decrease 50 *bp*		
☐	☐	Credit spreads:		
		Credit spreads increase 100 *bp*		
		Credit spreads decrease 100 *bp*		
☐	☐	Currency rates:		
☐	☐	Currency rates increase 10%		
		Currency rates decrease 10%		
☐	☐	*Commodity* prices:		
☐	☐	*Commodity* prices increase 10%		
		Commodity prices decrease 10%		
☐	☐	Option implied volatilities:		
		Implied volatilities increase 10 percentage points.		
		Implied volatilities decrease 10 percentage points.		
☐	☐	Default rates (*ABS*):		
		Default rates increase 10 percentage points		
		Default rates decrease 10 percentage points		
☐	☐	Default rates (*corporate bonds* and *CDS*):		
		Default rates increase 10 percentage points		
		Default rates decrease 10 percentage points		

48. [Reserved]

49. If you indicated more than one investment strategy for the *reporting fund* in Question 25 and you report performance results to current and prospective investors, counterparties, or otherwise, for one or more of the investment strategies reported in Question 25, report the gross performance results attributable to each such strategy during the *reporting period* in base currency terms.

You are required to provide monthly performance results only if such results are reported for the *reporting fund* (whether for purposes of reporting to current and prospective investors, counterparties, or otherwise). *You are not required to respond to this question if you report performance for the reporting fund as an internal rate of return.*

Investment Strategy	1st Month	2nd Month	3rd Month	Quarterly

Item D. Financing information

50. Financing liquidity:

(a) Provide the aggregate dollar amount of *borrowing* by and cash financing available to the *reporting fund* (including all drawn and

undrawn, committed and uncommitted lines of credit as well as any term financing).....

(b) Provide the dollar amount of financing that is available to the *reporting fund* but not used by type:

(i) *unsecured borrowing*……

(ii) *secured borrowing* via prime brokerage ….....

(iii) *secured borrowing* via *reverse repo* ……

(iv) other *secured borrowings* ……

(c) Divide the amount reported in response to part (a) among the periods specified below depending on the longest period for which the creditor is contractually committed to provide such financing.

(If a creditor (or syndicate or administrative/collateral agent) is permitted to vary unilaterally the economic terms of the financing or to revalue posted collateral in its own discretion and demand additional collateral, then the financing should be deemed uncommitted for purposes of this question. Uncommitted financing should be included under "1 day or less.")

(The total should add up to 100%.)

	% of total financing
1 day or less	
2 days – 7 days.....	
8 days – 30 days	
31 days – 90 days	
91 days – 180 days	
181 days – 365 days.....	
Longer than 365 days.....	

Item E. Investor information

51. (a) As of the *data reporting date*, what percentage of the *reporting fund's net asset value*, if any, is subject to a "side-pocket" arrangement? [ ]

(This question relates to whether assets are currently in a side-pocket and not the potential for assets to be moved to a side-pocket.)

(b) Have additional assets been placed in a side-pocket since the end of the prior *reporting period*?

(Check "NA" if you reported no assets under Question 51(a) in the current period and/or the prior period.)

☐ Yes ☐ No ☐ NA

52. [Reserved]

[ ]

53. Investor liquidity (as a % of *net asset value*):

(Divide the reporting fund's net asset value *among the periods specified below depending on the shortest period within which investors are entitled, under the fund documents, to withdraw invested funds or receive redemption payments, as applicable. Assume that you would impose gates where applicable but that you would not completely suspend withdrawals/redemptions and that there are no redemption fees. Please base on the notice period before the valuation date rather than the date proceeds would be paid to investors.)*

(The total should add up to approximately 100%.)

(For Question 53, please note that the standards for imposing suspensions and restrictions on withdrawals/redemptions may vary among funds. Make a good faith determination of the provisions that would likely be triggered during conditions that you view as significant market stress.)

	% of *NAV* locked for
1 day or less	
2 days – 7 days.....	
8 days – 30 days	
31 days – 90 days	
91 days – 180 days	
181 days – 365 days.....	
longer than 365 days.....	

Form PF Section 3	**Information about *liquidity funds* that you advise**

Section 3: Information about the *liquidity funds* that you advise

You must complete a separate Section 3 for each *liquidity fund* that you advise. However, with respect to *master-feeder arrangements* and *parallel fund structures*, you may report collectively or separately about the component funds as provided in the General Instructions.

Item A. *Reporting fund* identifying and operational information

54. (a) Name of the *reporting fund* .....

(b) *Private fund* identification number of the *reporting fund* .....

55. (a) Does the *reporting fund* seek to maintain a stable price per share?

☐ Yes ☐ No

(b) If yes, state the price the *reporting fund* seeks to maintain .....

Item B. *Reporting fund* assets

56. Provide the following information for each month of the *reporting period.*

	1st Month	2nd Month	3rd Month
(a) Net asset value of *reporting fund* as reported to current and prospective investors			
(b) Net asset value per share of *reporting fund* as reported to current and prospective investors *(to the nearest hundredth of a cent)*			
(c) Net asset value per share of *reporting fund (to the nearest hundredth of a cent; exclude the value of any capital support agreement or similar)*			
(d) *WAM* of *reporting fund (in days)*			
(e) *WAL* of *reporting fund (in days)*			
(f) *7-day gross yield* of *reporting fund (to the nearest hundredth of one percent)*			
(g) Dollar amount of the *reporting fund's* assets that are *daily liquid assets*			
(h) Dollar amount of the *reporting fund's* assets that are *weekly liquid assets*			
(i) Dollar amount of the *reporting fund's* assets that have a *maturity* greater than 397 days			

(j) Amount of cash held by the *reporting fund*			
(k) Total gross subscriptions (including divided reinvestments)			
(l) Total gross redemptions			

Form PF Section 3	**Information about *liquidity funds* that you advise** (to be completed by *large private fund advisers* only)

Item C. Financing information

57.

(a) Is the amount of total *borrowing* reported in response to Question 18 equal to or greater than 5% of the *reporting fund's net asset value*?

☐ Yes ☐ No

(b) If you responded "yes" to Question 57(a) above, divide the dollar amount of total *borrowing* reported in response to Question 18 among the periods specified below depending on the type of *borrowing*, the type of creditor and the latest date on which the *reporting fund* may repay the principal amount of the *borrowing* without defaulting or incurring penalties or additional fees.

(If a creditor (or syndicate or administrative/collateral agent) is permitted to vary unilaterally the economic terms of the financing or to revalue posted collateral in its own discretion and demand additional collateral, then the borrowing *should be deemed to have a maturity of 1 day or less for purposes of this question. For amortizing loans, each amortization payment should be treated separately and grouped with other borrowings based on its payment date.)*

(The total amount of borrowings reported below should equal approximately the total amount of borrowing *reported in response to Question 18.)*

	1 day or less	**2 days to 7 days**	**8 days to 30 days**	**31 days to 397 days**	**Greater than 397 days**
(i) *Unsecured borrowing*					
(A) *U.S. financial institutions*					
(B) *Non-U.S. financial institutions*					
(C) Other U.S. creditors					
(D) Other non-U.S. creditors					
(ii) *Secured borrowing*					
(A) *U.S. financial institutions*					
(B) *Non-U.S. financial institutions*					
(C) Other U.S. creditors					
(D) Other non-U.S. creditors					

58.

(a) Does the *reporting fund* have in place one or more committed liquidity facilities?

☐ Yes ☐ No

(b) If you responded "yes" to Question 60(a), provide the aggregate dollar amount of commitments under the liquidity facilities.....

Item D. Investor information

59. Specify the number of outstanding shares or units of the *reporting fund's* stock or similar securities .....

60. Is the *reporting fund* established as a cash management vehicle for other funds or accounts that you or your *affiliates* manage that are not cash management vehicles?

☐ Yes ☐ No

61. Provide the following information regarding investor concentration.

(For purposes of this question, if you know that two or more beneficial owners of the reporting fund are affiliated *with each other, you should treat them as a single beneficial owner.)*

(a) Specify the percentage of the *reporting fund's* equity that is beneficially owned by the beneficial owner having the largest equity interest in the *reporting fund*.....

(b) For each investor that beneficially owns 5% or more of the *reporting fund*'s equity, provide the following information. If you select "other" as an investor category, describe the investor in Question 4.

(i) Investor Category	**(ii) Investor's percent of equity of the *reporting fund* on the *data reporting date***
Drop-down menu of investor categories in Question 61]	
Drop-down menu of investor categories in Question 61]	
Et cetera.	

62. Provide a good faith estimate, as of the *data reporting date*, of the percentage of the *reporting fund's* outstanding equity that was purchased using *securities lending collateral*. .....

63. Provide the following information regarding the restrictions on withdrawals and redemptions by investors in the *reporting fund.*

(For Questions 63 and 64, please note that the standards for imposing suspensions and restrictions on withdrawals/redemptions may vary among funds. Make a good faith determination of the provisions that would likely be triggered during conditions that you view as significant market stress.)

As of the *data reporting date*, what percentage of the *reporting fund's net asset value*, if any:

(a) May be subjected to a suspension of investor withdrawals/redemptions by an adviser or fund governing body *(this question relates to an adviser's or governing body's right to suspend and not just whether a suspension is currently effective)*	
(b) May be subjected to material restrictions on investor withdrawals/redemptions (e.g., "gates") by an adviser or fund governing body *(this question relates to an adviser's or governing body's right to impose a restriction and not just whether a restriction been imposed)*	
(c) Is subject to a suspension of investor withdrawals/redemptions *(this question relates to whether a suspension is currently effective and not just an adviser's or governing body's right to suspend)*	
(d) Is subject to a material restriction on investor withdrawals/redemptions (e.g., a "gate") *(this question relates to whether a restriction has been imposed and not just an adviser's or governing body's right to impose a restriction)*	

64. Investor liquidity (as a % of *net asset value*):

(Divide the reporting fund's net asset value *among the periods specified below depending on the shortest period within which investors are entitled, under the fund documents, to withdraw invested funds or receive redemption payments, as applicable. Assume that you would impose gates where applicable but that you would not completely suspend withdrawals/redemptions and that there are no redemption fees. Please base on the notice period before the valuation date rather than the date proceeds would be paid to investors.*
The total should add up to 100%.)

	% of *NAV* locked for
1 day or less	
2 days – 7 days	
8 days – 30 days	
31 days – 90 days	
91 days – 180 days	
181 days – 365 days	
Longer than 365 days	

Item E. Portfolio Information

65. For each security held by the *reporting fund*, provide the following information for each month of the *reporting period*.

(a) Name of the issuer

(b) Title of the issue (including coupon, if applicable)

(c) CUSIP

(d) *LEI*, if available

(e) In addition to CUSIP and *LEI*, provide at least one of the following other identifiers, if available:

- ISIN

- CIK.....
- Other unique identifier (indicate identifier and type of identifier)

(f) The category of investment that most closely identifies the instrument .....

(Select from among the following categories of investment: U.S. Treasury Debt; U.S. Government Agency Debt; Non-U.S. Sovereign, Sub-Sovereign and Supra-National debt; Certificate of Deposit; Non-Negotiable Time Deposit; Variable Rate Demand Note; Other Municipal Security; Asset Backed Commercial Paper; Other Asset Backed Securities; U.S. Treasury Repurchase Agreement, if collateralized only by U.S. Treasuries (including Strips) and cash; U.S. Government Agency Repurchase Agreement, collateralized only by U.S. Government agency securities, U.S. Treasuries, and cash; Other Repurchase Agreement, if any collateral falls outside Treasury, Government Agency and cash; Insurance Company Funding Agreement; Investment Company; Financial Company Commercial Paper; Non-Financial Company Commercial Paper; or Tender Option Bond. If Other Instrument, include a brief description.)

(g) For repos, specify whether the repo is "open" (*i.e.*, the repo has no specified end date and, by its terms, will be extended or "rolled" each business day (or at another specified period) unless the investor chooses to terminate it), and provide the following information about the securities subject to the repo (*i.e.*, the collateral):

(If multiple securities of an issuer are subject to the repo, the securities may be aggregated, in which case provide: (i) the total principal amount and value and (ii) the range of maturity dates and interest rates.)

(i) Is the *repo* "open"? ..... ☐ Yes ☐ No

(ii) Is the *repo* centrally cleared? ☐ Yes ☐ No

(iii) If the *repo* is centrally cleared, identify the *CCP*.....

(iv) Is the *repo* settled on a tri-party platform? ☐ Yes ☐ No

(v) Name of the collateral issuer.....

(vi) CUSIP.....

(vii) *LEI*, if any.....

(viii) *Maturity* date.....

(ix) Coupon or yield.....

(x) The principal amount, to the nearest cent.....

(xi) Value of the collateral, to the nearest cent.....

(xii) The category of investment that most closely represents the collateral.....

(Select from among the following categories of investment: Asset-Backed Securities; Agency Collateralized Mortgage Obligations; Agency Debentures and Agency Strips; Agency Mortgage-Backed Securities; Private Label Collateralized Mortgage Obligations; Corporate Debt Securities; Equities; Money Market; U.S. Treasuries (including strips); Other Instrument. If Other Instrument, include a brief description, including, if applicable, whether it is a collateralized debt obligation, municipal debt, whole loan, or international debt).

(h) If the rating assigned by a *credit rating agency* played a substantial role in the *reporting fund's* (or its adviser's) evaluation of the quality, *maturity*, or liquidity of the security, provide the name

of each *credit rating agency* and the rating each assigned to the security.

(i) The *maturity* date used to calculate *WAM*.....

(j) The *maturity* date used to calculate *WAL*.....

(k) The ultimate legal *maturity* date (*i.e.*, the date on which, in accordance with the terms of the security without regard to any interest rate readjustment or *demand feature*, the principal amount must unconditionally be paid) .....

(l) If the security has a *demand feature* on which the *reporting fund* (or its adviser) is relying when evaluating the quality, *maturity*, or liquidity of the security, provide the following information:

(If the security does not have such a demand feature, enter "NA.")

(i) Identity of the *demand feature* issuer(s) .....

(ii) If the rating assigned by a *credit rating agency* played a substantial role in the *reporting fund's* (or its adviser's) evaluation of the quality, *maturity* or liquidity of the *demand feature*, its issuer, or the security to which it relates, provide the name of each *credit rating agency* and the rating assigned by each *credit rating agency* .....

(iii) The period remaining until the principal amount of the security may be recovered through the *demand feature* .....

(iv) The amount (*i.e.*, percentage) of fractional support provided by each *demand feature* issuer.....

(v) Whether the *demand feature* is a *conditional demand feature* .....

(m) If the security has a *guarantee* (other than an unconditional letter of credit reported in response to Question 65(l) above) on which the *reporting fund* (or its adviser) is relying when evaluating the quality, *maturity*, or liquidity of the security, provide the following information:

(If the security does not have such a guarantee*, enter "NA.")*

(i) Identity of the *guarantor(s)* .....

(ii) If the rating assigned by a *credit rating agency* played a substantial role in the *reporting fund's* (or its adviser's) evaluation of the quality, *maturity* or liquidity of the *guarantee*, the *guarantor*, or the security to which the *guarantee* relates, provide the name of each *credit rating agency* and the rating assigned by each *credit rating agency*……

(iii) The amount (*i.e.*, percentage) of fractional support provided by each *guarantor*.....

(n) If the security has any enhancements, other than those identified in response to Questions 65(l) and (m) above, on which the *reporting fund* (or its adviser) is relying when evaluating the quality, *maturity*, or liquidity of the security, provide the following information:

(If the security does not have such an enhancement, enter "NA.")

(i) Identity of the enhancement provider(s) .....

(ii) The type of enhancement(s) .....

(iii) If the rating assigned by a *credit rating agency* played a substantial role in the *reporting fund's* (or its adviser's) evaluation of the quality, *maturity* or liquidity of the enhancement, its provider, or the security to which it relates, provide the name of each *credit rating agency* used and the rating assigned by the *credit rating agency*…….

(iv) The amount (*i.e.*, percentage) of fractional support provided by each enhancement provider .....

(o) The yield of the security as of the reporting date:……..

(p) The total *value* of the *reporting fund's* position in the security, and separately, if the *reporting*

fund uses the amortized cost method of valuation, the amortized cost value, in both cases to the nearest cent:

(i) Including the value of any sponsor support.....

(ii) Excluding the value of any sponsor support.....

(q) The percentage of the *reporting fund's* net assets invested in the security, to the nearest hundredth of a percent.....

(r) Is the security categorized as a level 3 asset or liability in Question 20?

(s) Is the security a *daily liquid asset*?

(t) Is the security a *weekly liquid asset*?

(u) Is the security an *illiquid security*?

(v) Explanatory notes. Disclose any other information that may be material to other disclosures related to the portfolio security.

(If none, leave blank.)

Item F. Disposition of Portfolio Securities

66. Disclose the gross market value (to the nearest cent) of portfolio securities the *reporting fund* sold or disposed of during each month of the *reporting period* by category of investment. Do not include portfolio securities that the fund held until *maturity*.

Category of Investment	First Month	Second Month	Third Month
[Drop down menu of the category of investment]			
[Drop down menu of the category of investment]			
[Drop down menu of the category of investment]			

Category of Investment: *U.S. Treasury Debt; U.S. Government Agency Debt (if categorized as coupon-paying notes); U.S. Government Agency Debt (if categorized as no-coupon-discount notes); Non-U.S. Sovereign, Sub-Sovereign and Supra-National debt; Certificate of Deposit; Non-Negotiable Time Deposit; Variable Rate Demand Note; Other Municipal Security; Asset Backed Commercial Paper; Other Asset Backed Securities; U.S. Treasury Repo, if collateralized only by U.S. Treasuries (including Strips) and cash; U.S. Government Agency Repo, collateralized only by U.S. Government Agency securities, U.S. Treasuries, and cash; Other Repo, if any collateral falls outside Treasury, Government Agency and cash; Insurance Company Funding Agreement; Investment Company; Financial Company Commercial Paper; Non-Financial Company Commercial Paper; Tender Option Bond; or Other Instrument. If Other Instrument, include a brief description.*

Item G. Parallel Money Market Funds

67. If the *reporting fund* pursues substantially the same investment objective and strategy and invests side by side in substantially the same positions as a *money market fund* advised by you or any of your *related persons*, provide the *money*

market fund's EDGAR series identifier .....

(If neither you nor any of your related persons *advise such a* money market fund, *enter "NA.")*

Form PF Section 4	**Information about *private equity funds* that you advise**

Section 4: – Information about *private equity funds* that you advise.

You must complete a separate Section 4 for each *private equity fund* that you advise. However, with respect to *master-feeder arrangements* and *parallel fund structures*, you may report collectively or separately about the component funds as provided in the General Instructions.

Item A. *Reporting fund* identifying information

68.	(a)	Name of the *reporting fund*	
	(b)	*Private fund* identification number of the *reporting fund*	

Item B. Certain information regarding the *reporting fund*

69. Indicate the investment strategy in the drop-down menu that best describe the *reporting fund's* investment strategy by percent of deployed capital, during the *reporting period*. If the *reporting fund* engages in more than one strategy, provide a good faith estimate of the percentage of the *reporting fund's* deployed capital represented by each strategy.

(Select the investment strategy or strategies that best describe the reporting fund's strategies, even if the categories below do not precisely match your characterization of the reporting fund's strategy. If you report all or part of the reporting fund's strategy as "Other", explain in Question 4. The strategies listed are mutually exclusive (i.e., do not report the same portion of deployed capital in multiple strategies). The total should add to 100%.)

Strategy	% of capital
[drop-down menu]	

70. Identify, by ISO country code, each country to which the *reporting fund's* investments in portfolio companies represent exposure of 10% or more of the *reporting fund's net asset value.*

(See Instruction 15 for information on calculating the numerator for purposes of this question. You should categorize investments based on concentrations of risk and economic exposures.

Country	ISO code	% of NAV

Item C. *Reporting fund* and portfolio company financing;

71. Provide the following information regarding the *value* of the *reporting fund's borrowings* and the types of creditors.

(Do not net out amounts that the reporting fund loans to creditors or the value of collateral pledged to creditors. The percentages borrowed from the specified types of creditors should add up to approximately 100%.)

(a)	Dollar amount of total *borrowings*	
(b)	Percentage borrowed from *U.S. financial institutions*	
(c)	Percentage borrowed from *non-U.S. financial institutions*	
(d)	Percentage borrowed from U.S. creditors that are not financial institutions	
(e)	Percentage borrowed from non-U.S. creditors that are not financial institutions	

(f) Does the *reporting fund* borrow or have the ability to borrow at the fund-level as an alternative or complement to financing of portfolio companies? If so, check "yes' and complete subsection (g) of this question. Otherwise, check "no'

☐ Yes ☐ No

(g) For each type of *borrowing* or other cash financing available to the *reporting fund,* provide the total dollar amount available and the average amount borrowed over the reporting period.

Type of Financing	Total amount available (in dollars)	Average borrowed over the reporting period (in dollars)
□ Credit secured by the investments of the *reporting fund*		
□ Credit secured by *unfunded commitments*		
□ Credit secured by a combination of *unfunded commitments* and investments of the *reporting fund*.		
□ Other (explain in Question 4)		

72. (a) Do you or any of your *related persons* guarantee, or are you or any of your *related persons* otherwise obligated to satisfy, the obligations of any portfolio company in which the *reporting fund* invests?

(You are not required to respond "yes" simply because a portfolio company is a primary obligor and is also your related person*.)*

☐ Yes ☐ No

(b) If you responded "yes" to Question 72(a) above, report the total dollar *value* of all such *guarantees* and other obligations

73. What is the weighted average debt-to-equity ratio of the *controlled portfolio companies* in which the *reporting fund* invests *(expressed as a decimal to the tenths place)*?

(Weighting should be based on gross assets of each *controlled portfolio company* as a percentage of the aggregate gross assets of the *reporting fund's controlled portfolio companies.)*

73. What is the highest debt-to-equity ratio of any *controlled portfolio company* in

which the *reporting fund* invests *(expressed as a decimal to the tenths place)*?

74. What is the lowest debt-to-equity ratio of any *controlled portfolio company* in which the *reporting fund* invests *(expressed as a decimal to the tenths place)*?

75. What is the aggregate *gross asset value* of the *reporting fund's controlled portfolio companies*?

76. What is the aggregate principal amount of *borrowings* categorized as current liabilities on the most recent balance sheets of the *reporting fund's controlled portfolio companies*?

77. What is the aggregate principal amount of *borrowings* categorized as long-term liabilities on the most recent balance sheets of the *reporting fund's controlled portfolio companies*?

78. What percentage of the aggregate *borrowings* of the *reporting fund's controlled portfolio companies* is payment-in-kind (PIK) or zero-coupon debt? ☐

79. During the *reporting period*, did the *reporting fund* or any of its *controlled portfolio companies* experience an event of default under any of its indentures, loan agreements or other instruments evidencing obligations for borrowed money? If so, check "yes" and complete subsections (a) of this question. Otherwise, check "no".

(Do not include a potential event of default (i.e., an event that would constitute an event of default with the giving of notice, the passage of time or otherwise) unless it has become an event of default.)

☐ Yes ☐ No

(a) Identify the nature of the default event (check all that apply):

- ☐ Payment default of the *reporting fund*
- ☐ Payment default of a *controlled portfolio company*
- ☐ A default relating to a failure to uphold terms under the applicable borrowing agreement, other than a failure to make regularly scheduled payments.

80. (a) Does any *controlled portfolio company* of the *reporting fund* have in place one or more bridge loans or commitments (subject to customary conditions) for a bridge loan?

☐ Yes ☐ No

(b) If you responded "yes" to Question 80(a), identify each *person* that has provided all or part of any bridge loan or commitment to the relevant *controlled portfolio company*. For each such *person*, provide the applicable outstanding amount or commitment amount.

Legal Name of Counterparty	***LEI, if any***	**Indicate below if the counterparty is affiliated with a major financial institution**	**Outstanding amount of financing, if drawn**	**Amount of commitment, if undrawn**
[repeat drop-down list of creditor/counterparty names] Other:				
[repeat drop-down list of creditor/counterparty names] Other:				
[repeat drop-down list of creditor/counterparty names] Other:				

Item D. Portfolio company investment exposures

81. (a) Is any of the *reporting fund's controlled portfolio companies* a *financial industry portfolio company*?

☐ Yes ☐ No

(b) If you responded "yes" to Question 81(a), then for each of the *reporting fund's controlled portfolio companies* that constitutes a *financial industry portfolio company*, provide the following information.

Legal Name	**Address of principal office (include city, state and country)**	***NAICS code***	***LEI*, if any**	**Debt-to-equity ratio of portfolio company**	**Gross asset value of portfolio company**	**% of *reporting fund's* gross assets invested in this portfolio company**	**% of portfolio company beneficially owned by the *reporting fund***

82. Provide a breakdown of the *reporting fund's* investments in portfolio companies by industry, based on the *NAICS codes* of the companies.
(The total should add up to 100%.)

NAICS code	***% of reporting fund's total portfolio company investment***

83. If you or any of your *related persons* (other than the *reporting fund*) invest in any companies that are portfolio companies of the *reporting fund*, provide the aggregate dollar amount of these investments.

84. If the *reporting fund* effectuates (i) any *general partner clawback* or (ii) a *limited partner clawback or clawbacks* in excess of an aggregate amount equal to 10 percent of a fund's aggregate capital commitments, provide the following:

(a) Effective date:	
(b) Type of clawback (General Partner/Limited Partner):	
(c) Reason for clawback:	

85. You may provide any information you believe would be helpful in understanding the information reported in response to any question in this Section 4 of this form. Identify the related question for each comment *(use a drop-down menu so that notes are received in a structured format).*

Form PF Section 5	***Current report* for *large hedge fund advisers* to *qualifying hedge funds***

Section 5: Current report for large hedge fund advisers to qualifying hedge funds.

Upon the occurrence of any one or more of the events specified in Items B to I of this Section 5, you must file a current report responding to questions required by the applicable Item(s) (a "*current report*") as soon as practicable, but no later than 72 hours. The 72 hour period begins upon the occurrence of the event or when you reasonably believe the event occurred and you must respond to the best of your knowledge on the date of your *current report.* You may provide an additional explanation of the facts and circumstances relating to the event, including the causes and or proposed resolution in explanatory notes under Item J of this section 5.

In this Section 5, references to *most recent net asset value* mean the *net asset value* reported as of the *data reporting date*.

☐ Check here if you are filing an amendment to a previously filed *current report*. Provide the filing date of the *current report* you are amending [Drop-down list of Month, Day, Year, Time].

Item A: Information about you and the reporting fund

5-1 Provide your name and the other identifying information requested below.

(This should be your full legal name.)

Legal name	CRD Number	SEC 801-Number	*NFA* ID Number, if any	Large trader ID, if any	Large trader ID suffix, if any

5-2(a) Name of the *reporting fund*	
5-2(b) Private fund identification number of the *reporting fund*	
5-2(c) *NFA* identification number of the *reporting fund*, if applicable	
5-2(d) *LEI* of the *reporting fund*, if any	

5-3 Signatures of authorized representative (*see Instruction 11 to Form PF*)

I, the undersigned, sign this Section 5 on behalf of, and with the authority of, the *firm*. In addition, I sign this Section 5 on behalf of, and with the authority of, each of the *related persons* identified in Question 1(b) (other than any *related person* for which another individual has signed this Section 5 below).

Name of individual:	
Signature:	
Title	
Email address	
Telephone contact number (include area code and, if outside the United States, country code):	
Date	

Signature on behalf of *related persons:*
I, the undersigned, sign this Section 5 on behalf of, and with the authority of, the *related person(s)* identified below.
Name of each *related person* on behalf of which this individual is signing:

Name of individual:	
Signature:	
Title	
Email address	
Telephone contact number (include area code and, if outside the United States, country code):	
Date	

Item B. Extraordinary Investment Losses

If on any business day the 10-business-day *holding period return* of the *reporting fund* is less than or equal to -20%, provide the information required by Questions 5-4 to 5-7, below. *(Current reports should not be filed for overlapping 10-business-day periods.)*

5-4 Beginning date of the 10-business-day loss period:	
5-5 End date of the 10-business-day loss period:	
5-6 *Holding period return*:	
5-7 *Dollar amount of loss over the 10-business-day loss period*:	

Item C. Margin, Collateral or Equivalent Increase

If the total dollar value of margin, collateral, or an equivalent posted by the *reporting fund* at the end of a rolling 10-business-day period less the total dollar value of margin, collateral, or an equivalent posted by the *reporting fund* at the beginning of the rolling 10-business-day period is greater than or equal to 20% of the *average daily reporting fund aggregate calculated value* during the period, provide the following information (if the total value of margin, collateral or an equivalent posted by the *reporting fund* continues to increase, do not file another *current report* until on or after the next 10-business-day period beginning after the end date stated at 5-9 below.):

5-8 Beginning date of the 10-business-day period during which the increase was measured:	
5-9 End date of the 10-business-day period during which the increase was measured:	
5-10 Provide the total dollar value amount of margin, collateral or an equivalent posted by the *reporting fund* at the beginning of the 10-business-day period during which the increase was measured:	
5-11 Provide the total dollar value amount of margin, collateral or an equivalent posted by the *reporting fund* at the end of the 10-business-day period during which the increase was measured:	
5-12 Provide the *average daily reporting fund aggregate calculated value* of the *reporting fund* during the 10-business-day period during which the increase was measured:	

5-13 Counterparty or counterparties requiring increased margin, collateral or equivalent. *(If multiple counterparties are involved list them in order of the dollar amount of cumulative increase required by each counterparty.)*

Legal name of the counterparty	Counterparty *LEI*, if

	any
(a)	
(b)	
(c)	

5-14 Check one or more of the following to describe your current understanding of circumstances relating to the margin increase(s) (check all that apply):

- The increase is a result of exchange or *CCP* requirements or known regulatory action affecting the counterparty.
- A counterparty or counterparties independently increased the *reporting fund's* margin, collateral or equivalent requirements.
- The *reporting fund* established a new relationship or new business with one or more counterparties.
- The increase is attributable to new investment positions, investment approach or strategy and/or portfolio turnover of the *reporting fund*.
- The increase is related to a deteriorating position or positions in the *reporting fund's* portfolio or other credit trigger under applicable counterparty agreements.
- Other (provide explanation in Item J).

Item D. Notice of Margin Default or Determination of Inability to Meet a Call for Margin, Collateral or Equivalents

Provide the following information if you either (1) receive notification that the *reporting fund* is in default on a call for margin, collateral or an equivalent, resulting in a deficit that the *reporting fund* will not be able to cover or address by adding additional funds (in situations where there is a contractually agreed upon cure period an adviser would not be required to file an Item D *current report* until the expiration of the cure period unless the fund would not expect to be able to meet call during such cure period), provide the following information; or (2) if you determine that the *reporting fund* is unable to meet a call for increased margin, collateral or an equivalent, including in situations where there is a dispute regarding the amount or appropriateness of the margin call.

(*You are not required to file a current report in situations where you dispute the amount and appropriateness of a call for increased margin, collateral or an equivalent, provided the reporting fund has sufficient assets to meet the greatest of the disputed amounts.)*

(If you make this determination for more than one counterparty on the same day, provide the information required by 5-15 to 5-18 for each counterparty affected.)

5-15 Date of the notification or determination:	
5-16 Dollar amount of the call for margin, collateral or equivalent:	

5-17 Counterparty:

Legal name of the counterparty	Counterparty *LEI*, if any

5-18 Check one or more of the following to describe your current understanding of the circumstances relating to the default or your determination that the *reporting fund* is unable to meet a call for increased margin, collateral or an equivalent:

☐ A counterparty increased margin, collateral or equivalent requirements for the *reporting fund* contributed to the default or inability to meet a call for increased margin, collateral or an equivalent.

☐ Losses in the value of the *reporting fund's* portfolio or other credit trigger under applicable counterparty agreements contributed to the default or inability to meet a call for increased margin, collateral or an equivalent.

☐ A default or settlement failure of a counterparty contributed to the default or inability to meet a call for increased margin, collateral or an equivalent.

☐ Other (provide explanation in Item J).

Item E. Counterparty Default

If a counterparty to the *reporting fund* (1) does not meet a call for margin, collateral or equivalent or fails to make any other payment, in the time and form contractually required (taking into account any contractually agreed cure period), and (2) the amount involved is greater than 5% of the *reporting fund aggregate calculated value,* provide the following information.

(If you make this determination for more than one counterparty on the same day, provide the information required by 5-19 to 5-21 for each counterparty affected.)

5-19 Date of default:	
5-20 Dollar amount of default:	

5-21 Counterparty:

Legal name of the counterparty	Counterparty *LEI*, if any

Item F. Prime Broker Relationship Terminated or Materially Restricted

If (1) a prime broker terminates or materially restricts its relationship with the *reporting fund*, in whole or in part, in markets where that prime broker continues to be active; or (2) the relationship between the prime broker and the *reporting fund* was terminated by either the *reporting fund* or the prime broker in the last 72 hours or less in accordance with the section 5 current reporting period, and a termination event was activated in the prime brokerage agreement or related agreements, within the last 12 months provide the following information below. (Termination events, as specified in the prime broker agreement or related agreements, that are isolated to the financial state, activities or other *conditions* solely of the prime broker should not be considered for the purposes of this question.)

5-22 Date of the termination or material restriction:	
5-23 Date of the termination event(s) if different from date in 5-22:	

5-24 Prime Broker:

Legal name of the prime broker	Prime broker *LEI*, if any

Note: If a prime broker changes the terms of its relationship with the *reporting fund* in a way that significantly limits the fund's ability to operate under the terms of the original agreement, or significantly impairs the fund's ability to trade, the adviser should consider it a "material restriction" that would require filing of this Item F.

Item G. Operations Event

In this Item G, an "*operations event*" means that the *reporting fund* or *private fund adviser* experiences a significant disruption or degradation of the *reporting fund's critical operations*, whether as a result of an event at a service provider to the *reporting fund*, the *reporting fund*, or the adviser. For this purpose, "*critical operations*" means operations necessary for (i) the investment, trading, valuation, reporting, and risk management of the *reporting fund*; or (ii) the operation of the *reporting fund* in accordance with the Federal securities laws and regulations.

If there is an *operations event*, provide the following:

5-25 Date of the *operations event*, or date on which you estimate the event first occurred:	
5-26 Date *operations event* was discovered (discovery date may be same or different than the date of the event reported in 5-25):	

5-27 Check one or more of the following to describe your current understanding of circumstances relating to the *operations event* (check all that apply and provide supplementary information in Item J if desired):

- An *operations event* at a service provider to the *reporting fund* or the *private fund adviser* caused the *operations event* (in whole or in part) *(if applicable, provide the following information)*.

(a) Legal Name of Service Provider:	
(b) *LEI*, if any:	
(c) Identify services provided by the third party (e.g., fund accounting, administration, subadviser, accounting, custodial, other):	[drop-down menu]

- *An operations event* that occurred internally at the *reporting fund* or *reporting fund* adviser or a *related person*.
- *An operations event* that occurred related to a natural disaster or other *force majeure* event not within the control of the *private fund adviser.*
- Other (provide explanation in Item J).

5-28 Has the adviser initiated a disaster recovery or business continuity plan relating to the *operations event* and the continued operation of the adviser or the *reporting fund*?

☐ Yes ☐ No

5-29 Check one or more of the following to describe your current understanding of the impact of the *operations event* on the normal operations of *reporting fund (check all that apply)*:

- Disruption or degradation of trading of the *reporting fund's* portfolio assets
- Disruption or degradation of the valuation of the *reporting fund's* portfolio assets
- Disruption or degradation of your management of the *reporting fund's* investment risk
- Disruption or degradation of your ability to comply with applicable laws, rules, and regulations
- Other (provide explanation in Item J).

If technical or other difficulties resulting from the *operations event* prevent you from timely filing a *current report,* you may file as soon as practicable provided that you explain the technical or other difficulty that prevented timely filing in Item J of the *current report.*

Item H. Withdrawals and Redemptions

If the *reporting fund* receives cumulative requests for withdrawals or redemptions from the *reporting fund* equal to or more than 50% of the *most recent net asset value* (after netting against subscriptions and other contributions from investors received and contractually committed), provide the following information:

5-30 Date on which the net withdrawals or redemption requests exceeded 50% of the *most recent net asset value*:	
5-31 Net value of withdrawals or redemptions paid from the *reporting fund* between the last *data reporting date* and the date of this *current report*:	
5-32 Percentage of fund's *most recent net asset value* for which withdrawals or redemptions have been requested:	

5-33 Have you notified investors that the *reporting fund* will liquidate?

☐ Yes ☐ No

Item I. Unable to Satisfy Redemptions or Suspension of Redemptions

If the *reporting fund* (1) is unable to pay redemption requests, or (2) has suspended redemptions and the suspension lasts for more than 5 consecutive business days; provide the following information:

5-34 Date on which the *reporting fund* was unable to pay or suspended redemptions:	
5-35 Percentage of fund's *most recent net asset value* for which redemptions have been requested and not yet paid on the date of this *current report*:	

5-36 Have you notified investors that the *reporting fund* will liquidate?

☐ Yes ☐ No

Item J. Explanatory Notes

You may provide any information you believe would be helpful in understanding the information reported in response to any Item in this Section 5 of this form. Identify the related question for each comment *(use a drop-down menu so that notes are received in a structured format).*

Form PF Section 6	***Quarterly report for advisers to private equity funds***

Section 6: Quarterly report for advisers to *private equity funds*.

Upon the occurrence of any one or more of the events specified in Items B or C of this section 6, you must file a quarterly report responding to questions required by the applicable Item(s) (a "*private equity event report*"). If any of the below items occur within a particular fiscal quarter for the private equity funds you advise you will file a section 6 quarterly report within 60 calendar days after the end of each calendar quarter. Do not file a section 6 quarterly report if a *private equity reporting event* did not occur during that calendar quarter. It is not necessary to report the same instance of a reporting event again on future section 6 filings. You may provide an additional explanation of the facts and circumstances relating to the event, including the causes and/or proposed resolution in explanatory notes under Item D of this section 6.

☐ Check here if you are filing an amendment to a previously filed *current report*. Provide the filing date of the *current report* you are amending [Drop-down list of Month, Day, Year, Time].

Item A: Information about you and the reporting fund

6-1 Provide the identifying information requested below.

Full legal name	CRD Number	SEC 801-Number	*NFA* ID Number, if any	Large trader ID, if any	Large trader ID suffix, if any

6-2(a) Name of the *reporting fund*	
6-2(b) Private fund identification number of the *reporting fund*	
6-2(c) *NFA* identification number of the *reporting fund*, if any	
6-2(d) *LEI* of the *reporting fund*, if any	

6-3 Signatures of authorized representative (*see Instruction 11 to Form PF*)

I, the undersigned, sign this Section 6 on behalf of, and with the authority of, the *firm*. In addition, I sign this Section 6 on behalf of, and with the authority of, each of the *related persons* identified in Question 1(b) (other than any *related person* for which another individual has signed this Section 6 below).

Name of individual:	
Signature:	
Title:	
Email address:	
Telephone contact number (include area code and, if outside the United States, country code):	
Date:	

Signature on behalf of *related persons:*
I, the undersigned, sign this Section 6 on behalf of, and with the authority of, the *related person(s)* identified below.

Name of individual:	
Signature:	
Title:	
Email address:	

Telephone contact number (include area code and, if outside the United States, country code):	
Date:	

Item B. Adviser-Led Secondary Transactions.

If the *reporting fund* closed an *adviser-led secondary transaction*, provide the following:

6-4 Closing date of transaction:	
6-5 Description of transaction:	

Item C. General Partner Removal, Termination of the Investment Period or Termination of Fund.

Upon receipt by the *reporting fund* or its adviser or *affiliate* of notification that fund investors have removed the adviser or its *affiliate* as the general partner or similar control person of the *reporting fund*, elected to terminate the *reporting fund's* investment period, or elected to terminate the *reporting fund*, in each case, as contemplated by the *reporting fund's* governing documents (each, a "*removal event*") provide the following:

6-6 Effective date of *removal event*:	
6-7 Description of *removal event*:	

Item D. Explanatory Notes

You may provide any information you believe would be helpful in understanding the information reported in response to any Item in this Section 6 of this form. Identify the related question for each comment *(use a drop-down menu so that notes are received in a structured format).*

Form PF Section 7	**Request for temporary hardship exemption** (to be completed by *private fund advisers* requesting exemption)

Section 7: Request for temporary hardship exemption

You must complete Section 7 if you are requesting a temporary hardship exemption pursuant to *SEC* rule 204(b)-1(f).

A. For which type of Form PF filing are you requesting a temporary hardship exemption?

1. If you <u>are not</u> a *large hedge fund adviser* or *large liquidity fund adviser*:
   - ☐ Initial filing
   - ☐ *Annual update*
   - ☐ Final filing
2. If you <u>are</u> a *large hedge fund adviser* or *large liquidity fund adviser*:
   - ☐ Initial filing
   - ☐ *Quarterly update*
   - ☐ Filing to transition to annual reporting
   - ☐ Final filing

B. Provide the following information regarding your request for a temporary hardship exemption (attach a separate page if additional space is needed).

1. Describe the nature and extent of the temporary technical difficulties when you attempt to submit the filing to the Form PF filing system on the IARD:

2. Describe the extent to which you previously have submitted documents in electronic format with the same hardware and software that you are unable to use to submit this filing:

3. Describe the burden and expense of employing alternative means (e.g., a service provider) to submit the filing in electronic format in a timely manner:

4. Provide any other reasons that a temporary hardship exemption is warranted:

Form PF: Glossary of Terms

GLOSSARY OF TERMS

7-day gross yield	Based on the 7 days ended on the *data reporting date*, calculate the *liquidity fund*'s yield by determining the net change, exclusive of capital changes and income other than investment income, in the value of a hypothetical pre-existing account having a balance of one share at the beginning of the period and dividing the difference by the value of the account at the beginning of the base period to obtain the base period return, and then multiplying the base period return by (365/7) with the resulting yield figure carried to the nearest hundredth of one percent. The *7-day gross yield* should not reflect a deduction of shareholders fees and fund operating expenses.
10-year bond equivalent	For interest rate sensitive positions, the equivalent position in a 10-year zero coupon bond, expressed in U.S. dollars.
ABCP	Asset backed commercial paper, including (but not limited to) structured investment vehicles, single-seller conduits and multi-seller conduit programs. Do not include any positions held via *CDS* (these should be recorded in the *CDS* category).
ABS	Securities derived from the pooling and repackaging of cash flow producing financial assets.
Adjusted exposure	The *value* of positions after netting as specified by instructions to Question 32.
Adviser-led secondary transaction	Any transaction initiated by the adviser or any of its related persons that offers private fund investors the choice to: (i) sell all or a portion of their interests in the private fund; or (ii) convert or exchange all or a portion of their interests in the private fund for interests in another vehicle advised by the adviser or any of its related persons.
Advisers Act	U.S. Investment Advisers Act of 1940, as amended.
Affiliate	With respect to any *person*, any other *person* that directly or indirectly *controls*, is *controlled* by or is under common *control* with such person. The term *affiliated* means that two or more *persons* are *affiliates*.
Agency securities	Any security issued by a *person* controlled or

	supervised by and acting as an instrumentality of the government of the United States pursuant to authority granted by the Congress of the United States and guaranteed as to principal or interest by the United States. Include bond derivatives and positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund or entity).
AIF	An alternative investment fund that is not regulated under the UCITS Directive, as defined in the Directive of the European Parliament and of the Council on alternative investment fund managers (No. 2011/61/EU), as amended, or an alternative investment fund that is captured by the Alternative Investment Fund Managers (Amendment etc.) (EU Exit) Regulations 2019, as amended.
Annual update	An update of this Form PF with respect to any fiscal year.
Average daily reporting fund aggregate calculated value	The average of the daily *reporting fund aggregate calculated value* for the end of the business day on business days one through ten of the reporting period.
Borrowing and collateral received (“*B/CR”)*	The mark-to-market value, as of the *data reporting date,* of the following: (i) *cash and cash equivalents* received as *borrowing,* (ii) securities *borrowed* or received by the *reporting fund* (include securities borrowed in connection with short sales, securities lending and *repo*), (iii) collateral posted by a counterparty to the *reporting fund's* account, (iv) negative market-to-market value of derivatives (from the *reporting fund's* point of view), and (v) the *gross notional value* of *synthetic long positions.*
Borrowings	*Secured borrowings* and *unsecured borrowings*, collectively. *Borrowings* by a *reporting fund* include, but are not limited to (i) *cash and cash equivalents* received with an obligation to repay; (ii) securities lending transactions (count *cash and cash equivalents* and securities received by the *reporting fund* in the transaction, including securities borrowed by the *reporting fund* for short sales); (iii) *repo* or *reverse repo* (count *cash and cash equivalents* and securities received by the *reporting fund);* (iv) negative mark-to-market of

	derivative transactions from the *reporting fund*'s point of view; and (v) the *gross notional value* of *synthetic long positions.*
bp	Basis points.
Cash and cash equivalents	Cash (including U.S. and non-U.S. currencies) and cash equivalents. For purposes of this definition, cash equivalents are: (i) bank deposits, certificates of deposit, bankers acceptances and similar bank instruments held for investment purposes; (ii) the net cash surrender value of an insurance policy; or (iii) investments in *money market funds*. Do not include any digital asset in *cash and cash equivalents.*
Cash borrowing entries	For Questions 26 and 41, the sum of amounts attributable to an individual counterparty included the entries on the following lines of the *reporting fund's consolidated counterparty exposure table*: (a) *unsecured borrowing – cash and cash equivalents,* (b)(i) *cash and cash equivalents* received by the *reporting fund* in margin loans and securities lending transactions, (c)(i) *cash and cash equivalents* received by the *reporting fund* related to *repo* and *reverse repo* (include tri-party repo), (d)(i) *cash and cash equivalents* received by the *reporting fund* related to other *secured borrowing,* (e)(i) — negative mark to market exposure of derivative positions cleared by a *CCP* and (f)(i) and (ii) *gross notional value* of *synthetic long positions* and negative mark to market exposure of uncleared derivative positions (not cleared by a *CCP*).
Cash lending entries	For Questions 26 and 41, the sum of amounts attributable to an individual counterparty included the entries on the following lines of the *reporting fund's consolidated counterparty exposure table*: (b)(i) – *cash and cash equivalents* posted by *reporting fund* to the counterparty in margin borrowing and securities lending transactions, (c)(i) – *cash and cash equivalents* posted by the *reporting fund* relating to *repo* and *reverse repo* (include tri-party repo), (d)(i) – *cash and cash equivalents* posted by the *reporting fund* relating to other *secured borrowing,* (e)(i) – positive mark to market exposure in

	derivative positions cleared by a *CCP,* and (f)(i) and (ii) – *gross notional value* of *synthetic short positions* and positive mark to market exposure in uncleared derivative positions (not cleared by a *CCP*).
CCP	Central clearing counterparties (or central clearing houses) (for example, CME Clearing, The Depository Trust & Clearing Corporation, Fedwire and LCH Clearnet Limited).
CDO	Collateralized debt obligations (including cash flow and synthetic). Do not include any positions held via *CDS* (these should be recorded in the *CDS* category).
CDS	Credit default swaps, including any *LCDS*.
CEA	U.S. Commodity Exchange Act, as amended.
CFTC	U.S. Commodity Futures Trading Commission.
CLO	Collateralized loan obligations (including cash flow and synthetic) other than *MBS*. Do not include any positions held via *CDS* (these should be recorded in the *CDS* category).
Closed-end private fund	Any *private fund* that only issues securities, the terms of which do not provide a holder with any right, except in extraordinary circumstances, to withdraw, redeem, or require the repurchase of such securities, but which may entitle holders to receive distributions made to all holders *pro rata*.
Collateral posted entries	For Question 26, the sum of amounts attributable to an individual counterparty included the entries on the following lines of the *reporting fund's consolidated counterparty exposure table*: (b)(ii) - *cash and cash equivalents* posted by the *reporting fund* as collateral for derivatives under a cross-margining agreement; (b)(iii) - *government securities* and other securities posted by the *reporting fund* to the counterparty in margin borrowing, securities lending transactions, and as margin for derivatives under any cross-margining agreement; (c)(ii) - *government securities* and other securities posted by the *reporting fund* relating to *repo* and *reverse repo* (include tri-party repo), (d)(ii) - *government securities* and other securities posted by the *reporting fund* relating to other *secured borrowing*,

(e)(ii) and (iii) - *cash and cash equivalents, government securities* and other securities posted by the *reporting fund* as collateral relating to derivative positions cleared by a *CCP* and
(f)(iii) and (iv) - *cash and cash equivalents, government* securities and other securities posted by the *reporting fund* as collateral relating to uncleared derivative positions (not cleared by a *CCP)*.

For Question 41, entries on the following lines of the *reporting fund's counterparty credit exposure and collateral table*:
(b)(ii) — *cash and cash equivalents* posted by the *reporting fund* as collateral for derivatives under a cross-margining agreement,
(b)iii), and (iv) *government securities* and other securities posted by the *reporting fund* to the counterparty in margin borrowing, securities lending transactions, and as margin for derivatives under any cross-margining agreement,
(c)(ii)— *government securities* and other securities posted by the *reporting fund* relating to *repo* and *reverse repo* (include tri-party repo),
(d)(ii) — *government securities* and other securities posted by the *reporting fund* relating to other *secured borrowing*,
(e)(ii), (iii), and (iv) – *cash and cash equivalents, government securities* and other securities posted by the *reporting fund* as collateral relating to derivative positions cleared by a *CCP*, and
(f)(iii), (iv), and (v) — *cash and cash equivalents, government securities* and other securities posted by the *reporting fund* as collateral relating to uncleared derivative positions (not cleared by a *CCP*).

Collateral received entries

For Question 26, the sum of amounts attributable to an individual counterparty included the entries on the following lines of the *reporting fund's consolidated counterparty exposure table*:
(b)(ii) — *cash and cash equivalents* received by the *reporting fund* as collateral for derivatives under any cross-margining agreement,
(b)(iii) — *government securities* and other securities received by the *reporting fund* in cash margin borrowing and securities lending transactions,
(c)(ii) — *government securities* and other securities received by the *reporting fund* related to *repo* and *reverse repo* (include tri-party repo),
(d)(ii) — *government securities* and other securities received related to other *secured borrowing*,
(e)(ii) and (iii) – *cash and cash equivalents,*

	government securities and other securities received as collateral in derivative positions cleared by a *CCP* and (f)(iii) and (iv) — *cash and cash equivalents, government securities* and other securities received as collateral in uncleared derivative positions (not cleared by a *CCP*). For Question 41, entries on the following lines of the *reporting fund's counterparty credit exposure and collateral table*: (b)(ii) — *cash and cash equivalents* received by the *reporting fund* as collateral for derivatives under any cross-margining agreement, (b)(iii) and (iv) — *government securities* and other securities received by the *reporting fund* in cash margin borrowing and securities lending transactions, (c)(ii) and (iii) — *government securities* and other securities received by the *reporting fund* related to *repo* and *reverse repo* (include tri-party repo), (d)(ii) and (iii) — *government securities* and other securities received related to other *secured borrowing*, (e)(ii), (iii), and (iv) – *cash and cash equivalents, government securities* and other securities received as collateral in derivative positions cleared by a *CCP* and (f)(iii), (iv) and (v) — *cash and cash equivalents, government securities* and other securities received as collateral in uncleared derivative positions (not cleared by a *CCP*).
Combined money market and liquidity fund assets under management	With respect to any adviser, the sum of: (i) such adviser's *liquidity fund assets under management*; and (ii) such adviser's *regulatory assets under management* that are attributable to *money market funds* that it advises.
Committed capital	Any commitment pursuant to which a *person* is obligated to acquire an interest in, or make capital contributions to, the *private fund*.
Commodities	Has the meaning provided in the *CEA*. For questions regarding *commodities*, provide the *value* of all exposure to *commodities* that you hold physically, synthetically or through derivatives (whether cash or physically settled), or indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund or entity).

Commodity pool	A "commodity pool," as defined in section 1a(10) of the *CEA*.
Conditional demand feature	Has the meaning provided in *rule 2a-7*.
Consolidated counterparty exposure table	For hedge funds, other than *qualifying hedge funds*, the Section 1c table (at Question 26) that collects the *reporting fund's borrowing and collateral received* and *lending and posted collateral* aggregated across all creditors and counterparties as of the end of the *reporting period.* For *qualifying hedge funds*, the Section 2 table (at Question 41) that collects the *reporting fund's borrowing and collateral received* and *lending and posted collateral* aggregated across all creditors and counterparties as of the end of the *reporting period.*
Control	Has the meaning provided in *Form ADV*. The term *controlled* has a corresponding meaning.
Controlled portfolio company	With respect to any *private equity fund*, a portfolio company that is *controlled* by the *private equity fund*, either alone or together with the *private equity fund's affiliates* or other *persons* that are, as of the *data reporting date*, part of a club or consortium including the *private equity fund*.
Convertible bonds	Convertible *corporate bonds* (not yet converted into shares or cash). Include bond derivatives, but do not include any positions held via *CDS* (these should be recorded in the *CDS* category). Include positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund or entity).
Corporate bonds	Bonds, debentures, and notes, including commercial paper, issued by corporations and other non-governmental entities.

	Do not include preferred equities. Include bond derivatives, but do not include any positions held via *CDS* (these should be recorded in the *CDS* category). Include positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund or entity).
Correlation derivative	A derivative transaction for which the underlying asset is the correlation between the price or rate movements of two instruments.
CPO	A "commodity pool operator," as defined in section 1a(11) of the *CEA*.
Credit rating agency	Any nationally recognized statistical rating organizations, as that term is defined in section 3(a)(62) of the Securities Exchange Act of 1934.
Critical operations	For purposes of responding to Section 5, means the operations necessary for (i) the investment, trading, valuation, reporting, and risk management of the *reporting fund*; or (ii) the operation of the *reporting fund* in accordance with the Federal securities laws and regulations.
CTA	A "commodity trading advisor," as defined in section 1a(12) of the *CEA*.
Current report	A *current report* provided pursuant to the items listed in Section 5 of Form PF.
Current reporting event	Any event that triggers the requirement to complete and file a *current report* pursuant to the items in Section 5 of Form PF.
Daily liquid assets	Has the meaning provided in *rule 2a-7*.
Daily rate-of-return	Is the percentage change in the *reporting fund aggregate calculated value* from one day to the next and adjusted for subscriptions and redemptions, if necessary.
Data reporting date	If you are a *large hedge fund adviser* or a *large liquidity fund adviser* responding to Items on this Form PF relating to any *hedge fund* or *liquidity fund*, the *data reporting date* is the last calendar day of the most recently completed calendar quarter for all Items on Form PF relating to such *hedge funds* and *liquidity funds*. If you are filing an initial filing or *annual update* for any other *private fund*, the *data reporting*

	date is the last calendar day of your most recently completed fiscal year.
Demand feature	Has the meaning provided in *rule 2a-7*.
Dependent parallel managed account	With respect to any *private fund*, any related *parallel managed account* other than a *parallel managed account* that individually (or together with other *parallel managed accounts* that pursue substantially the same investment objective and strategy and invest side by side in substantially the same positions) has a *gross asset value* greater than the *gross asset value* of such *private fund* (or, if such *private fund* is a *parallel fund*, the *gross asset value* of the *parallel fund structure* of which it is a part).
Dollar amount of loss over the 10-business-day period	Is equal to the *reporting fund aggregate calculated value* at the end of the 10-business-day loss period less the *reporting fund aggregate calculated value* at the beginning of the 10-business day loss period less the net of any subscriptions or redemptions during the 10-business-day period.
ETF	Exchange-traded fund.
Exchange traded products	An investment traded on a stock exchange that invests in underlying securities or assets, such as an *ETF* or exchange traded note.
Exempt reporting adviser	Has the meaning provided in *Form ADV*.
Exotic CDS	*CDS*s referencing bespoke baskets or tranches of *CDOs*, *CLOs*, and other structured investment vehicles, including credit default tranches.
External private funds	*Private funds* that neither you nor your *related persons* advise.
Feeder fund	See *master-feeder arrangement*.
Financial industry portfolio company	Any of the following: (i) a nonbank financial company, as defined in the Financial Stability Act of 2010; or (ii) any bank, savings association, bank holding company, financial holding company, savings and loan holding company, credit union or other similar company regulated by a Federal, state, or foreign banking regulator, including the

	Federal Deposit Insurance Corporation, the Board of Governors of the Federal Reserve System, the Office of the Comptroller of the Currency, the National Credit Union Administration or the Farm Credit Administration.
Firm	The *private fund adviser* completing or amending this Form PF.
Foreign exchange derivative	Any derivative whose underlying asset is a currency other than the base currency of the *reporting fund* or is an exchange rate. Cross-currency interest rate swaps and currency forwards should be included in *foreign exchange derivatives* and excluded from *interest rate derivatives*. If one leg of the *foreign exchange derivative* is the base currency of the *private fund*, only the foreign currency side of the transaction should be counted. If neither leg of the *foreign exchange derivative* is in the base currency, both legs should be counted.
Form ADV	Form ADV, as promulgated and amended by the *SEC*.
Form ADV Section 7.B.1 General partner clawback	Section 7.B.1 of Schedule D to *Form ADV*. Any obligation of the general partner, its related persons, or their respective owners or interest holders to restore or otherwise return *performance-based compensation* to the fund pursuant to the fund's governing agreements.
General partner stakes investing	An investment strategy that acquires non-controlling interests in alternative investment managers and other entities that provide advisory services to, or receive compensation from, private funds.
G10	The Group of Ten. If the composition of the *G10* has changed after the effective date of this Form PF, use the current composition of the *G10*.
Government entity	Has the meaning provided in *Form ADV*.
Government securities	Are: (i) *U.S. treasury securities*; (ii) *agency securities*; and (iii) any certificate of deposit for any of the foregoing.
Gross asset value	Value of gross assets, calculated in accordance with Part 1A, Instruction 6.e(3) of *Form ADV*.
Gross exposure	The sum of the absolute value of all of the *reporting fund's* long and short positions with legal and contractual rights to a *reference asset*.
Gross notional value	The nominal or notional value of all transactions

	that have been entered into but not yet settled as of the *data reporting date*. For contracts with variable nominal or notional principal amounts, the basis for reporting is the nominal or notional principal amounts as of the *data reporting date* computed as the number of shares or units of the underlying *reference asset* times current price on the *data reporting date.*
Gross reporting fund aggregate calculated value	The sum of the absolute value of every position in the *reporting fund's* portfolio, including *cash and cash equivalents*, short positions, and any fund-level borrowing, with the most recent price or value applied to the position for purposes of managing the investment portfolio. Where one or more portfolio positions are valued less frequently than daily, the last price used should be carried forward, though a current foreign exchange rate may be applied if the position is not valued in U.S. dollars. It is not necessary to adjust the *gross reporting fund aggregate calculated value* for accrued fees or expenses. *Gross reporting fund aggregate calculated values* do not need to be subjected to fair valuation procedures. The inclusion of income accruals is recommended but not required; however, the approach should be consistent over time. The *gross reporting fund aggregate calculated value* may be calculated using the adviser's own internal methodologies and conventions of the adviser's service providers, provided that these are consistent with information reported internally. *But see reporting fund aggregate calculated value.*
GSE bonds	Notes, bonds, and debentures issued by private entities sponsored by the U.S. federal government but not guaranteed as to principal and interest by the U.S. federal government. Include GSE *MBS.* Include bond derivatives, but <u>do not</u> include any positions held via *CDS* (these should be recorded in the *CDS* category). Include positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund, or entity).
Guarantee	For purposes of Question 65, has the meaning provided in paragraph (a)(16)(i) of *rule 2a-7*.
Guarantor	For purposes of Question 65, the provider of any *guarantee.*

Hedge fund	Any *private fund* (other than a *securitized asset fund*): (a) with respect to which one or more investment advisers (or related persons of investment advisers) may be paid a performance fee or allocation calculated by taking into account unrealized gains (other than a fee or allocation the calculation of which may take into account unrealized gains solely for the purpose of reducing such fee or allocation to reflect net unrealized losses); (b) that may borrow an amount in excess of one-half of its *net asset value* (including any *committed capital*) or may have gross notional exposure in excess of twice its *net asset value* (including any *committed capital*); or (c) that may sell securities or other assets short or enter into similar transactions (other than for the purpose of hedging currency exposure or managing duration). Solely for purposes of this Form PF, any commodity pool about which you are reporting or required to report on Form PF is categorized as a hedge fund. For purposes of this definition, do not net long and short positions. Include any *borrowings* or notional exposure of another person that are guaranteed by the private fund or that the private fund may otherwise be obligated to satisfy.
Hedge fund assets under management	With respect to any adviser, *hedge fund assets under management* are the portion of such adviser's *regulatory assets under management* that are attributable to *hedge funds* that it advises.
Holding period return	Means the cumulative *daily rate-of-return* over the holding period calculated by geometrically linking the *daily rates-of-return*. Holding period return (%) = $(((1 + R_1) \times (1 + R_2) \ldots (1 + R_{10})) - 1) \times 100$ where R_1, R_2 … $R1_0$ are the *daily rates-of-return* during the holding period expressed as decimals.
Illiquid security	Has the meaning provided in *rule 2a-7.*
Index CDS	*CDSs* referencing a standardized basket of credit entities, including *CDS* indices and indices referencing *leveraged loans*.
Individual counterparty exposure table	The tables at Questions 41 and42 that collect the *reporting fund's borrowing and collateral received* and *lending and posted collateral* for each identified creditors and other counterparties as of the end of the *reporting period.*

Inflation derivative	A derivative transaction for which the underlying asset is the rate of inflation in a given country, or the price or yield of inflation-linked debt securities.
Instrument type	The instrument types specified by Question 32.
Interest rate derivative	Any derivative whose underlying asset is the obligation to pay or the right to receive a given amount of money accruing interest at a given rate. Cross-currency interest rate swaps should be included in *foreign exchange derivatives* and excluded from *interest rate derivatives*. This information must be presented in terms of the *10-year bond equivalents.*
Internal private funds	*Private funds* that you or any of your *related persons* advise.
Internal rate of return	The discount rate that causes the net present value of all cash flows throughout the life of the fund to be equal to zero. *But see, rate of return.*
Investment grade	A security is *investment grade* if it is sufficiently liquid that it can be sold at or near its carrying value within a reasonably short period of time and is subject to no greater than moderate credit risk.
Investments in non-U.S. registered investment companies	Investments in investment companies (other than *private funds, money market funds*, and *ETFs*) organized outside the U.S. and not registered as investment companies under the Investment Company Act of 1940.
Investments in other sub-asset classes	Any investment not included in another *sub-asset class*.
ISDA	International Swaps and Derivatives Association
Large hedge fund adviser	Any *private fund adviser* that is required to file Section 2 of Form PF for a *qualifying hedge fund*. See Instruction 3 to determine whether you are required to file this section.
Large liquidity fund adviser	Any *private fund adviser* that is required to file Section 3 of Form PF. See Instruction 3 to determine whether you are required to file this section.
Large private equity fund adviser	Any *private fund adviser* that is required to file Section 4a of Form PF. See Instruction 3 to determine whether you are required to file this section.

Large private fund adviser	Any *large hedge fund adviser*, *large liquidity fund adviser*, or *large private equity fund adviser*.
LCDS	Loan credit default swaps.
LEI	With respect to any company, the "legal entity identifier" assigned by or on behalf of an internationally recognized standards setting body and required for reporting purposes by the U.S. Department of the Treasury's Office of Financial Research or a financial regulator. Do not substitute any other identifier that does not meet this definition.
Lending and posted collateral (*L/PC)*	The mark-to-market value, as of the *data reporting date*, of the following: (i) *cash and cash equivalents* received by a counterparty from the *reporting fund* with the obligation to repay (exclude portfolio investments), (ii) securities borrowed or received by a counterparty in a *reverse repo* or securities lending transaction, (iii) collateral posted by the *reporting fund* to a counterparty, (iv) positive mark-to-market value of derivatives (from the *reporting fund*'s point of view), and (v) *gross notional value* of *synthetic short positions*. Do not include in lending and posted collateral any portfolio holdings or transactions for investment purposes, such as debt or equity securities issued by a counterparty, or the credit exposure of the *reporting fund* obtained by making secured or unsecured loans or similar transactions as part of the *reporting fund's* investment strategy. For example, in the case of an option on a debt security, report counterparty credit exposure in respect of the positive or negative mark-to-market value of the option and associated posted collateral; do not report the credit risk of the underlying debt security.
Leveraged loans	Loans that are made to entities whose senior unsecured long term indebtedness is *non-investment grade*. This may include loans made in connection with the financing structure of a leveraged buyout. Do not include any positions held via *LCDS* (these should be recorded in the *CDS* category). Include positions held indirectly through another entity (e.g., through an *ETF*, *exchange traded product*, U.S. registered investment companies, *non-U.S. registered investment companies*, *internal private fund* or *external private fund*, commodity pool, or

	other company, fund or entity).
Limited partner clawback	An obligation of a fund's investors to return all or any portion of a distribution made by the fund to satisfy a liability, obligation, or expense of the fund pursuant to the fund's governing agreements.
Liquidity fund	Any private fund that seeks to generate income by investing in a portfolio of short term obligations in order to maintain a stable *net asset value* per unit or minimize principal volatility for investors.
Liquidity fund assets under management	With respect to any adviser, *liquidity fund assets under management* are the portion of such adviser's *regulatory assets under management* that are attributable to *liquidity funds* it advises (including *liquidity funds* that are also *hedge funds*).
Listed equity	Equities, including preferred equities, listed on a regulated exchange. Include synthetic or derivative exposures to equities. Include positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund, or entity).
Listed equity derivatives	All synthetic or derivative exposures to equities, including preferred equities, listed on a regulated exchange. Include *e.g.*, single stock futures, equity index futures, derivatives relating to ADRs, and *other derivatives* relating to indices on *listed equities*, dividend swaps, total return swaps (contracts for difference), warrants, and rights.
Master-feeder arrangement	An arrangement in which one or more funds ("*feeder funds"*) invest all or substantially all of their assets in a single *private fund* ("*master fund"*). A fund would also be a *feeder fund* investing in a *master fund* for purposes of this definition if it issued multiple classes (or series) of shares or interests and each class (or series) invests substantially all of its assets in a single *master fund*.
Master fund	See *master-feeder arrangement*.
Maturity	The maturity of the relevant asset, determined without reference to the maturity shortening

	provisions contained in paragraph (i) of *rule 2a-7* regarding interest rate readjustments.
MBS	Mortgage backed securities, including residential, commercial and agency. Do not include any positions held via *CDS* (these should be recorded in the *CDS* category).
Money market fund	Has the meaning provided in *rule 2a-7*.
Most recent net asset value	The *net asset value* reported as of the *data reporting date* at the end of the *reporting fund's* most recent *reporting period.*
NAICS code	With respect to any company, the six-digit North American Industry Classification System code that best describes the company's primary business activity and principal source of revenue. If the company reports a business activity code to the U.S. Internal Revenue Service, you may rely on that code for this purpose.
Net assets under management	*Net assets under management* are your *regulatory assets under management* minus any outstanding indebtedness or other accrued but unpaid liabilities.
Net asset value or *NAV*	With respect to any *reporting fund*, the gross assets reported in response to Question 12 minus any outstanding indebtedness or other accrued but unpaid liabilities.
Netted exposure	The *reporting fund's* exposure to a *reference asset,* after netting under instructions at Question 39.
NFA	The National Futures Association.
Non-investment grade	A security is *non-investment grade* if it is not an *investment grade* security.
Non-U.S. financial institution	Any of the following: (i) a financial institution chartered outside the United States; (ii) a financial institution that is separately incorporated or otherwise organized outside the United States but has a parent that is a financial institution chartered in the United States; or (iii) a branch or agency that resides in the United States but has a parent that is a financial institution chartered outside the United States.
Open-end private fund	Any *private fund* that offers redemption rights to its investors in the ordinary course, which may be paid in cash or in kind, irrespective of redemption frequency or notice periods and without regard to

	any suspensions, gates, lock-ups, or side pockets that may be employed by the fund.
Operations event	Means for purposes of section 5 that the *reporting fund* or *adviser* experiences a significant disruption or degradation of the *reporting fund's critical operations*, whether as a result of an event at a service provider to the *reporting fund*, the *reporting fund*, or the *adviser.*
OTC	With respect to any instrument, the trading of that instrument over the counter.
Other ABS	*ABS* products that are not covered by another *sub-asset class*.
Other commodities	*Commodities* other than agriculture, base metals, crude oil, natural gas, gold, other (non-gold) precious metals, and power and other energy commodities. For questions regarding *other commodities*, provide the *value* of all exposure to *other commodities* that you hold physically, synthetically or through derivatives (whether cash or physically settled), and positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund, or entity).
Other derivatives	Any derivative not included as another *instrument type or sub-asset class*.
Other private fund	Any *private fund* that is not a *hedge fund, liquidity fund, private equity fund, real estate fund, securitized asset fund* or *venture capital fund*.
Other structured products	Any *structured products* not included in another *sub-asset class*. Do not include any positions held via *CDS* (these should be recorded in the *CDS* category).
Parallel fund	See *parallel fund structure*.
Parallel fund structure	A structure in which one or more *private funds* (each, a "*parallel fund*") pursues substantially the same investment objective and strategy and invests side by side in substantially the same positions as another *private fund*.

Parallel managed account	With respect to any *private fund*, a *parallel managed account* is any managed account or other pool of assets that you advise and that pursues substantially the same investment objective and strategy and invests side by side in substantially the same positions as the identified *private fund*.
Performance-based compensation	Allocations, payments, or distributions of capital based on the *reporting fund*'s (or any of its investments') capital gains, capital appreciation and/or other profit.
Person	Has the meaning provided in *Form ADV*.
Position calculated value	The value of a portfolio position using the most recent price or value available for purposes of managing the investment portfolio. Where a given position is valued less frequently than daily, the last price used should be carried forward, though a current foreign exchange rate may be applied if the position is not valued in the *reporting fund's* base currency. *Position calculated values* do not need to be subjected to fair valuation procedures. The *position calculated value* may be calculated using the adviser's own internal methodologies and conventions of the adviser's service providers, provided that these are consistent with information reported internally.
Principal office and place of business	Has the meaning provided in *Form ADV*.
Private equity event report	A quarterly report provided pursuant to the items listed in Section 6 of Form PF.
Private equity fund	Any *private fund* that is not a *hedge fund, liquidity fund, real estate fund*, *securitized asset fund* or *venture capital fund* and does not provide investors with redemption rights in the ordinary course.
Private equity fund assets under management	With respect to any adviser, *private equity fund assets under management* are the portion of such adviser's *regulatory assets under management* that are attributable to *private equity funds* it advises.
Private equity reporting event	Any event that triggers the requirement to complete and file a *private equity event report* pursuant to the items in Section 6 of Form PF.
Private fund	Any issuer that would be an investment company as defined in section 3 of the Investment Company Act of 1940 but for section 3(c)(1) or 3(c)(7) of that Act. If any *private fund* has issued two or more series (or classes) of equity interests whose values are determined with respect to separate portfolios of

	securities and other assets, then each such series (or class) should be regarded as a separate *private fund*. This only applies with respect to series (or classes) that you manage as if they were separate funds and not a fund's side pockets or similar arrangements.
Private fund adviser	Any investment adviser that (i) is registered or required to register with the *SEC* (including any investment adviser that is also registered or required to register with the *CFTC* as a *CPO* or *CTA*) and (ii) advises one or more *private funds*.
Private fund assets under management	With respect to any adviser, *private fund assets under management* are the portion of such adviser's *regulatory assets under management* that are attributable to *private funds* it advises.
Qualifying hedge fund	Any *hedge fund* that has a *net asset value* (individually or in combination with any *feeder funds, parallel funds* and/or *dependent parallel managed accounts*) of at least $500 million as of the last day of any month in the fiscal quarter immediately preceding your most recently completed fiscal quarter.
Quarterly update	An update of this Form PF with respect to any calendar quarter.
Rate of return	For a *reporting fund*, the *rate of return* is the percentage change in the *net asset value* (or, when a *net asset value* is not available, in the *reporting fund aggregate calculated value*) in the *reporting fund*'s base currency from one date to another and adjusted for subscriptions and redemptions. For a portfolio position, the *rate of return* is the percentage change in the *position calculated value*, adjusted for income earned and for changes in the quantity held resulting from activity, such as purchases, sales, or splits. *But see, internal rate of return.*
Real estate fund	Any *private fund* that is not a *hedge fund*, that does not provide investors with redemption rights in the ordinary course and that invests primarily in real estate and real estate related assets.
Reference asset	A security or other investment asset to which the *reporting fund* is exposed through direct ownership (*i.e.*, a physical or cash position), synthetically (*i.e.*, the subject of a derivative or similar instrument held by the *reporting fund*), or indirect ownership *(e.g., through ETFs,* other *exchange traded products,* U.S. registered investment companies, *non-U.S. registered investment*

	companies, internal private funds, external private funds, commodity pools, or other companies, fund or entities. In the case of futures contracts permitting multiple deliverable assets, the *reference asset* should be the then-current cheapest to deliver instrument. You may identify the *reporting fund's reference assets* according to your internal methodologies and the conventions of service providers, provided that these methodologies and conventions are consistently applied and do not conflict with any instructions or guidance relating to this Form, and reported information is consistent with information you report internally and to investors and counterparties.
Regulatory assets under management	Regulatory assets under management, calculated in accordance with Part 1A, Instruction 5.b of *Form ADV*.
Related person	Has the meaning provided in *Form ADV*.
Repo	Any purchase of securities coupled with an agreement to sell the same (or similar) securities at a later date at an agreed upon price (*i.e.*, a "securities in" transaction). Do not include any positions held via *CDS* (these should be recorded in the *CDS* category).
Reporting fund	A *private fund* as to which you must report information on Form PF. Typically, each *private fund* is a *reporting fund*.

Reporting fund aggregate calculated value	Every position in the *reporting fund's* portfolio, including *cash and cash equivalents*, short positions, and any fund-level borrowing, with the most recent price or value applied to the position for purposes of managing the investment portfolio. *The reporting fund aggregate calculated value* is a signed value where all position values are summed. Where one or more portfolio positions are valued less frequently than daily, the last price used should be carried forward, though a current foreign exchange rate may be applied if the position is not valued in U.S. dollars. It is not necessary to adjust the *reporting fund aggregate calculated value* for accrued fees or expenses. *Reporting fund aggregate calculated value* does not need to be subjected to fair valuation procedures. The inclusion of income accruals is recommended but not required; however, the approach should be consistent over time. The *reporting fund aggregate calculated value* may be calculated using the adviser's own internal methodologies and conventions of the adviser's service providers, provided that these are consistent with information reported internally. *But see gross reporting fund aggregate calculated value.*
Reporting period	With respect to an *annual update*, the twelve month period ending on the *data reporting date*. With respect to a *quarterly update*, the three month period ending on the *data reporting date*.
Reverse repo	Any sale of securities coupled with an agreement to repurchase the same (or similar) securities at a later date at an agreed upon price (*i.e.*, a "securities out" transaction).
RSSD ID	The identifier assigned by the National Information Center of the Board of Governors of the Federal Reserve System, if any.
Rule 2a-7	Rule 2a-7 promulgated by the *SEC* under the Investment Company Act of 1940.
SEC	U.S. Securities and Exchange Commission.
Secured borrowing	Obligations for borrowed money in respect of which the borrower has posted collateral or other credit support. For purposes of this definition, *reverse repos* are *secured borrowings*.
Securities lending collateral	Cash pledged to the *reporting fund's* beneficial owners as collateral in respect of securities lending arrangements.

Securitized asset fund	Any *private fund* whose primary purpose is to issue asset backed securities and whose investors are primarily debt holders.
Separately operated	For purposes of this Form, a *related person* is *separately operated* if you are not required to complete Section 7.A. of Schedule D to *Form ADV* with respect to that *related person*.
Single name CDS	*CDSs* referencing a single entity. Includes sovereign *single name CDS,* financial institution *single name CDS,* and other *single name CDS.*
Sovereign bonds	Any notes, bonds and debentures issued by a national government (including central governments, other governments and central banks but excluding U.S. state and local governments), whether denominated in a local or foreign currency. Include bond derivatives, but do not include any positions held via *CDS* (these should be recorded in the *CDS* category). Include positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund or entity).
Structured products	Pre-packaged investment products, typically based on derivatives and including structured notes.
Sub-asset class	Each sub-asset class identified in Question 32.
Synthetic long position	A total return derivative or similar contract under which (i) the *reporting fund* receives returns of a risky *reference asset* in exchange for paying the returns of a different, riskless *reference asset*, or (ii) the *reporting fund* sells deep-in-the-money (e.g., those with deltas of 98% or higher) puts on a risky *reference asset* in exchange for an option premium. Total return derivatives may include, for example, a derivative that receives the total return or credit spread of equity or debt securities issued by individual issuers, or baskets or indices of such securities, including swaps, forwards, deep-in-the-money options (e.g., those with deltas of 98% or higher) and credit default swaps which receive the credit spread (also sometimes described as "short credit protection"). Exclude total return derivatives that have been cleared through a *CCP*; include uncleared *OTC* derivative positions only. Include derivatives providing the return of equity

	securities, real estate, digital assets, commodities, *sovereign bonds*, *corporate bonds*, municipal bonds, and other assets. Do not include *interest rate derivatives, volatility derivatives, variance derivatives* or *foreign exchange derivatives*. Do not include deep-in-the-money call options (e.g., those with deltas of 98% or higher) purchased by the *reporting fund* if the *reporting fund* has already paid the option premium in full, but include them if the premium is being paid over time.
Synthetic short position	A total return derivative or similar contract under which (i) the *reporting fund* pays returns of a risky *reference asset* in exchange for receiving the returns of a different, riskless *reference asset*, or (ii) the *reporting fund* sells deep-in-the-money calls (e.g., those with deltas of 98% or higher) on a risky *reference asset* in exchange for an option premium. Total return derivatives may include, for example, a derivative where the fund pays the total return or credit spread of equity or debt securities issued by individual issuers, or baskets or indices of such securities, including swaps, forwards, deep-in-the-money options (e.g., those with deltas of 98% or higher), and credit default swaps which pay the credit spread (also sometimes described as "long credit protection"). Exclude total return derivatives that have been cleared through a *CCP*; include uncleared *OTC* derivative positions only. Include derivatives where the fund pays the return of equity securities, real estate, digital assets, commodities, *sovereign bonds*, *corporate bonds*, municipal bonds and other assets. Do not include *interest rate derivatives, volatility derivatives, variance derivatives* or *foreign exchange derivatives*. Do not include deep-in-the-money put options (e.g., those with deltas of 98% or higher) purchased by the *reporting fund* if the *reporting fund* has already paid the option premium in full; do include them if the premium is being paid over time.
Trading vehicle	A separate legal entity, wholly or partially owned by one or more *reporting funds,* that holds assets, incurs leverage, or conducts trading or other activities as part of a *reporting fund's* investment activities but does not operate a business.
UCITS	Undertakings for Collective Investment in Transferable Securities, as defined in the UCITS Directive of the European Parliament and of the Council (No. 2009/65/EC), as amended, or as captured by the Collective Investment Schemes

	(Amendment etc.) (EU Exit) Regulations 2019, as amended.
Unencumbered cash	The sum of the *private fund's* (i) *cash and cash equivalents, (ii) government securities, and (iii)* the *value* of overnight *repos* used for liquidity management where the assets purchased are *U.S. treasury securities* or *agency securities* minus the sum of the following (without duplication): (i) *cash and cash equivalents* and *government securities* transferred to a collateral taker pursuant to a title transfer arrangement; and (ii) *cash and cash equivalents* and *government securities* subject to a security interest, lien or other encumbrance (this could include *cash and cash equivalents* and *government securities* in an account subject to a control agreement).
Unfunded commitments	*Committed capital* that has not yet been contributed to the *reporting fund* by investors.
United States person	Has the meaning provided in rule 203(m)-1 under the *Advisers Act*, which includes any natural person that is resident in the United States.
Unlisted equity	Equities, including preferred equities that are not listed on a regulated exchange. Include synthetic or derivative exposures to equities and positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund, or entity).
Unsecured borrowing	Obligations for borrowed money in respect of which the borrower has not posted collateral or other credit support.
U.S. depository institution	Any U.S. domiciled depository institution, including any of the following: (i) a depository institution chartered in the United States, including any federally-chartered or state-chartered bank, savings bank, cooperative bank, savings and loan association, or an international banking facility established by a depositary institution chartered in the United States; (ii) banking offices established in the United States by a financial institution that is not organized or chartered in the United States, including a branch or agency located in the United States and engaged in banking not incorporated separately from its financial institution parent, United States subsidiaries established to engage in international business, and international banking

	facilities; (iii) any bank chartered in any of the following United States affiliated areas: U.S. territories of American Samoa, Guam, and the U.S. Virgin Islands; the Commonwealth of the Northern Mariana Islands; the Commonwealth of Puerto Rico; the Republic of the Marshall Islands; the Federated States of Micronesia; and the Trust Territory of the Pacific Islands (Palau); or (iv) a credit union (including a natural person or corporate credit union).
U.S. financial institution	Any of the following: (i) a financial institution chartered in the United States (whether federally-chartered or state-chartered); (ii) a financial institution that is separately incorporated or otherwise organized in the United States but has a parent that is a financial institution chartered outside the United States; or (iii) a branch or agency that resides outside the United States but has a parent that is a financial institution chartered in the United States.
U.S. treasury securities	Direct obligations of the U.S. Government. Include *U.S. treasury security* derivatives. Include positions held indirectly through another entity (e.g., through an *ETF, exchange traded product,* U.S. registered investment companies, *non-U.S. registered investment companies, internal private fund or external private fund, commodity pool*, or other company, fund or entity).
Value	See Instruction 15.
VaR	For a given portfolio, the loss over a target horizon that will not be exceeded at some specified confidence level.
Variance derivative	A derivative transaction for which the underlying asset is the price or yield variance of one or more assets or indices.
Venture capital fund	Any *private fund* meeting the definition of venture capital fund in rule 203(l)-1 of the *Advisers Act*.
Volatility derivative	A derivative transaction for which the underlying asset is the price or yield volatility of one or more assets or indices.
WAL	Weighted average portfolio maturity of a *liquidity fund* calculated taking into account the maturity shortening provisions contained in paragraph (i) of *rule 2a-7*, but determined without reference to the exceptions in paragraph (i) of *rule 2a-7* regarding interest rate readjustments with the dollar-weighted average based on the percentage of each security's

	market value in the portfolio.
WAM	Weighted average portfolio maturity of a *liquidity fund* calculated taking into account the maturity shortening provisions contained in paragraph (i) of *rule 2a-7* with the dollar-weighted average based on the percentage of each security's market value in the portfolio.
Weekly liquid assets	Has the meaning provided in *rule 2a-7*. Include *daily liquid assets*. As a result, the value of *weekly liquid assets* should equal or exceed the value of *daily liquid assets*.

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Note: The following Commodity Futures Trading Commission (CFTC) appendices will not appear in the Code of Federal Regulations.

CFTC Appendices to Form PF; Reporting Requirements for All Filers and Large Hedge Fund Advisers—CFTC Voting Summary and Commissioners' Statements

CFTC Appendix 1—Voting Summary

On this matter, Chairman Behnam and Commissioners Johnson and Goldsmith Romero voted in the affirmative. Commissioners Mersinger and Pham voted in the negative.

CFTC Appendix 2—Statement of Commissioner Kristin N. Johnson

Transparency is an integral component of the regulatory framework that ensures the safety and soundness and enduring preeminence of our financial markets. Our statutory mandate expressly directs the Commodity Futures Trading Commission's (Commission or CFTC) mission to ''ensure the financial integrity of all transactions subject to [the Commodity Exchange Act] and the avoidance of systemic risk'' and today, consistent with this mandate, the Commission seeks to enhance oversight and improve visibility through well-calibrated data collection approaches.[1]

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) incorporated innovative regulatory features for promoting the stability of the U.S. financial system, including establishing the Financial Stability Oversight Council (FSOC) to monitor for emerging systemic risks that may significantly impact our financial markets and American consumers. Congress, in drafting the Dodd-Frank Act, recognized that systemic risks are best monitored through collaboration among prudential and market regulators, each endowed with distinct regulatory mandates and empowered to leverage their expertise to support FSOC's systemic risk oversight objectives.

Specifically, Section 404 of the Dodd-Frank Act amends Section 204 of the Investment Advisers Act of 1940 (Advisers Act) and grants the Securities and Exchange Commission (SEC) the power to require an SEC-registered investment adviser to file with the SEC reports regarding ''private funds advised by the investment adviser, as necessary and appropriate in the public interest and for the protection of investors, or for the assessment of systemic risk by the [FSOC].'' [2] Section 406 of the Dodd-Frank Act, which amends Section 211 of the Advisers Act, instructs the SEC and Commission, after consultation with FSOC, to ''jointly promulgate rules to establish the form and content of the reports required to be filed'' with the SEC and Commission by investment advisers registered both under the Advisers Act and the Commodity Exchange Act.[3]

As directed by the Dodd-Frank Act, in 2011, the Commission and SEC jointly issued rules to provide FSOC with important information about private fund operations and strategies through Form PF.[4] Form PF is a confidential form for certain SEC-registered investment advisers to private funds, including those that may also be dually registered with the Commission as a commodity pool operator (CPO) or commodity trading advisor (CTA).[5] In 2022, the Commission and SEC adopted proposed amendments to Form PF.[6] As noted in the preamble, the Commission is adopting the joint final rule to amend Form PF (Final Rule) in an effort to address information gaps and improve the Commissions' and FSOC's understanding of the private fund industry and the potential systemic risk posed by it. The Final Rule seeks to clarify aspects of the form and instructions as well as remove certain questions to streamline reporting.

Appropriately-tailored regulatory disclosure is a powerful tool in identifying vulnerabilities and trends in our markets, mitigating systemic risk, and addressing financial stability concerns. Disclosure of financial information to market regulators is critical to the regulatory oversight of our financial markets, particularly when such disclosure is accurate, timely, robust, and usable. Effective disclosure enables regulators to monitor market activities and take swift, decisive action to prevent or manage market stresses and crises. I support today's Final Rule and the careful consideration of both agencies that it reflects.

I commend the work of the staff of the Market Participants Division—Amanda Olear, Pamela Geraghty, Michael Ehrstein, Elizabeth Groover, and Andrew Ruggiero—for their careful work on the Final Rule.

CFTC Appendix 3—Dissenting Statement of Commissioner Caroline D. Pham

I respectfully dissent from the Joint Final Rule on Form PF and Reporting Requirements for All Filers and Large Hedge Fund Advisers that is being issued together with the U.S. Securities

[1] 7 U.S.C. 5(b).

[2] 15 U.S.C. 80b–4(b).

[3] 15 U.S.C. 80b–11(e).

[4] Reporting by Investment Advisers to Private Funds and Certain Commodity Pool Operators and Commodity Trading Advisors on Form PF, 76 FR 71128, 71129 (Nov. 16, 2011).

[5] In 2020, the Commission adopted amendments to Form CPO–PQR for CPOs, which is used by CPOs and CTAs for reporting purposes. In lieu of filing the CFTC's Form CPO–PQR, CPOs and CTAs may file NFA Form PQR, a comparable form required by the National Futures Association.

[6] Form PF; Reporting Requirements for All Filers and Large Hedge Fund Advisers, 87 FR 53832 (Sept. 1, 2022).

and Exchange Commission (SEC) (SEC–CFTC Joint Final Rule on Form PF or Joint Final Rule) because, overall, the rule does not achieve its stated purpose to improve systemic risk monitoring because it will obscure hidden risks and unacceptably increase costs for American savers.

When this proposal was adopted in August 2022, I raised my concerns that in a time of economic challenges, including rising inflation, we must be careful when considering proposals that could inhibit positive economic activity that supports American businesses and jobs.[1] The SEC–CFTC Joint Final Rule on Form PF charges ahead on the wrong path with no consideration for these concerns.

Astoundingly, all rules since the financial crisis have been based on aggregating data for better risk management.[2] Yet the SEC–CFTC Joint Final Rule on Form PF continues to mandate double, and sometimes triple, reporting,[3] without being based on any demonstrated data or evidence that it will improve systemic risk monitoring. To the contrary, it will hinder the ability of both firms and regulators to truly identify hidden risk. Effective risk management requires aggregation to understand the risk exposure. Indeed, this is a key pillar of Dodd-Frank reforms. But the Joint Final Rule will force firms to disaggregate risk monitoring and reporting to the individual fund level—obscuring the full picture.

Even worse, the SEC–CFTC Joint Final Rule on Form PF will create a flood of new information of dubious utility that will generate too much noise and is detrimental to data quality, also making it harder to see real risk positions. And, the Joint Final Rule does nothing to address the many operational and practical implementation issues that will unacceptably increase costs for American savers who have worked hard to earn their retirement investments.

For all these reasons, I cannot support the SEC–CFTC Joint Final Rule on Form PF and must dissent. This is an unacceptable backsliding on the progress made since the Dodd-Frank Act to strengthen our financial system, mitigate systemic risk, and promote financial stability.

I appreciate the time that the staff spent with my office on this rulemaking. I would like to thank the CFTC team of Andrew Ruggiero, Elizabeth Groover, Michael Ehrstein, and Pamela Geraghty in the Market Participants Division for their efforts.

[FR Doc. 2024–03473 Filed 3–11–24; 8:45 am]

BILLING CODE 8011–01–P; 6351–01–P

[1] Dissenting Statement of Commissioner Caroline D. Pham Regarding the Proposed Amendments to Form PF (Aug. 10, 2022). I also continue to believe the cost-benefit analysis in the Final Rule is insufficient.

[2] *See e.g.,* Prohibitions and Restrictions on Proprietary Trading and Certain Interests in, and Relationships With, Hedge Funds and Private Equity Funds, 79 FR 5808 (Jan. 31, 2014), available at *https://www.federalregister.gov/documents/2014/01/31/2013-31476/prohibitions-and-restrictions-on-proprietary-trading-and-certain-interests-in-and-relationships-with;* Bank for International Settlements (BIS) Basel Committee on Banking Supervision, Standards for Minimum Capital Requirements for Market Risk (Jan. 2016), available at *https://www.bis.org/bcbs/publ/d352.pdf.* BIS revised the Standards in 2019. BIS Basel Committee on Banking Supervision, Standards for Minimum Capital Requirements for Market Risk (Jan. 2019; rev. Feb. 2019), available at *https://www.bis.org/bcbs/publ/d457.pdf.*

[3] An overriding basis for the CFTC and SEC joint final rule in 2011 was to support the Financial Stability Oversight Council (FSOC), but three overlapping, or identical, data sets across the three entities raises confidentiality and data protection concerns, along with inefficiency issues. *See* Joint Final Rule, Reporting by Investment Advisers to Private Funds and Certain Commodity Pool Operators and Commodity Trading Advisors on Form PF, 76 FR 71128, 71129 (Nov. 16, 2011), available at *https://www.federalregister.gov/documents/2011/11/16/2011-28549/reporting-by-investment-advisers-to-private-funds-and-certain-commodity-pool-operators-and-commodity; see also* Authority To Require Supervision and Regulation of Certain Nonbank Financial Companies, 77 FR 21637, 21644 (Apr. 11, 2012), available at *https://www.federalregister.gov/documents/2012/04/11/2012-8627/authority-to-require-supervision-and-regulation-of-certain-nonbank-financial-companies.*

FEDERAL REGISTER

Vol. 89 Tuesday,
No. 49 March 12, 2024

Part IV

Department of Energy

10 CFR Part 430
Energy Conservation Program: Energy Conservation Standards for Consumer Clothes Dryers; Final Rule and Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2014–BT–STD–0058]

RIN 1904–AF59

Energy Conservation Program: Energy Conservation Standards for Consumer Clothes Dryers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Direct final rule.

SUMMARY: The Energy Policy and Conservation Act, as amended (''EPCA''), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including consumer clothes dryers. In this direct final rule, DOE is adopting amended energy conservation standards for consumer clothes dryers. DOE has determined that the amended energy conservation standards for these products would result in significant conservation of energy and are technologically feasible and economically justified.

DATES: The effective date of this rule is July 10, 2024. If adverse comments are received by July 1, 2024 and DOE determines that such comments may provide a reasonable basis for withdrawal of the direct final rule under 42 U.S.C. 6295(o), a timely withdrawal of this rule will be published in the **Federal Register**. If no such adverse comments are received, compliance with the amended standards established for consumer clothes dryers in this direct final rule is required on and after March 1, 2028. Comments regarding the likely competitive impact of the standards contained in this direct final rule should be sent to the Department of Justice contact listed in the **ADDRESSES** section on or before April 11, 2024.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2014-BT-STD-0058.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

The U.S. Department of Justice Antitrust Division invites input from market participants and other interested persons with views on the likely competitive impact of the standards contained in this direct final rule. Interested persons may contact the Antitrust Division at *energy.standards@usdoj.gov* on or before the date specified in the **DATES** section. Please indicate in the ''Subject'' line of your email the title and Docket Number of this direct final rule.

FOR FURTHER INFORMATION CONTACT:

Dr. Carl Shapiro, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–5649. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Matthew Schneider, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 597–6265. Email: *Matthew.Schneider@hq.doe.gov.*

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I. Synopsis of the Direct Final Rule

The Energy Policy and Conservation Act, Public Law 94–163, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B of EPCA [2] established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include consumer clothes dryers, the subject of this direct final rule. (42 U.S.C. 6292(a)(7))

Pursuant to EPCA, any new or amended energy conservation standard must, among other things, be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

In light of the above and under the authority provided by 42 U.S.C. 6295(p)(4), DOE is issuing this direct final rule amending energy conservation standards for consumer clothes dryers.

The adopted standard levels in this direct final rule were proposed in a letter submitted to DOE jointly by groups representing manufacturers, energy and environmental advocates, consumer groups, and a utility. This letter, titled ''Energy Efficiency Agreement of 2023'' (hereafter, the ''Joint Agreement'',) [3] recommends specific energy conservation standards for consumer clothes dryers that, in the commenters' view, would satisfy the EPCA requirements in 42 U.S.C. 6295(o). DOE subsequently received letters of support from States—including New York, California, and Massachusetts [4]—and utilities—including San Diego Gas and Electric (''SDG&E'') and Southern California Edison (''SCE'') [5]—advocating for the adoption of the recommended standards.

In accordance with the direct final rule provisions at 42 U.S.C. 6295(p)(4), DOE has determined that the recommendations contained in the Joint Agreement are compliant with 42 U.S.C. 6295(o). As required by 42 U.S.C. 6295(p)(4)(A)(i), DOE is also simultaneously publishing elsewhere in this **Federal Register** a notice of proposed rulemaking (''NOPR'') that contains standards identical to those adopted in this direct final rule. Consistent with the statute, DOE is providing a 110-day public comment period on the direct final rule. (42 U.S.C. 6295(p)(4)(B)) If DOE determines that any comments received provide a reasonable basis for withdrawal of the direct final rule under 42 U.S.C. 6295(o) or any other applicable law, DOE will publish the reasons for withdrawal and continue the rulemaking under the NOPR. (42 U.S.C. 6295(p)(4)(C)) *See* section II.A of this document for more details on DOE's statutory authority.

The amended standards that DOE is adopting in this direct final rule are the efficiency levels recommended in the Joint Agreement (shown in Table I.1). The standards are expressed in terms of the combined energy factor (''CEF_{D2}''), measured in pounds per kilowatt-hour (''lb/kWh''), as determined in accordance with DOE's consumer clothes dryer test procedure at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix D2 (''appendix D2''). The CEF metric includes active mode, standby mode, and off mode energy use. The amended standards recommended in the Joint Agreement are represented as trial standard level (''TSL'') 3 (hereinafter the ''Recommended TSL'') and are described in section V.A of this document. The Joint Agreement's standards for consumer clothes dryers apply to all products listed in Table I.1 and manufactured in, or imported into, the United States starting on March 1, 2028.

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[3] Available at *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0055.*

[4] Available at *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0056.*

[5] Available at *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0057.*

TABLE I.1—ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

[Compliance starting March 1, 2028]

Product class	Minimum CEFD2 (lb/kWh)
(i) Electric, Standard (4.4 cubic feet (''ft³'') or greater capacity)	3.93
(ii) Electric, Compact (120 volts (''V'')) (less than 4.4 ft³ capacity)	4.33
(iii) Vented Electric, Compact (240V) (less than 4.4 ft³ capacity)	3.57
(iv) Vented Gas, Standard (4.4 ft³ or greater capacity)	3.48
(v) Vented Gas, Compact (less than 4.4 ft³ capacity)	2.02
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft³ capacity)	2.68
(vii) Ventless Electric, Combination Washer-Dryer	2.33

A. Benefits and Costs to Consumers

Table I.2 summarizes DOE's evaluation of the economic impacts of the adopted standards on consumers of consumer clothes dryers, as measured by the average life-cycle cost (''LCC'') savings and the simple payback period (''PBP'').[6] The average LCC savings are positive for all product classes, and the PBP is less than the average lifetime of consumer clothes dryers, which is estimated to be 14 years (*see* section IV.F of this document).

TABLE I.2—IMPACTS OF ADOPTED ENERGY CONSERVATION STANDARDS ON CONSUMERS OF CONSUMER CLOTHES DRYERS

Consumer clothes dryer class	Average LCC savings (2022$)	Simple payback period (years)
Electric, Standard (4.4 ft³ or greater capacity)	$252	0.6
Electric, Compact (120V) (less than 4.4 ft³ capacity)	66	2.2
Vented Electric, Compact (240V) (less than 4.4 ft³ capacity)	90	2.0
Vented Gas, Standard (4.4 ft³ or greater capacity)	102	1.9
Ventless Electric, Compact (240V) (less than 4.4 ft³ capacity)	99	0.4
Ventless Electric, Combination Washer-Dryer	11	0.0

DOE's analysis of the impacts of the adopted standards on consumers is described in section IV.F of this document.

B. Impact on Manufacturers

The industry net present value (''INPV'') is the sum of the discounted cash flows to the industry from the base year (2024) through the end of the analysis period, which is 30 years from the analyzed compliance date.[7] Using a real discount rate of 7.5 percent, DOE estimates that the INPV for manufacturers of consumer clothes dryers in the case without amended standards is $2.12 billion in 2022$.[8] Under the adopted standards, which align with the Recommended TSL for consumer clothes dryers, DOE estimates the change in INPV to range from −6.8 percent to −5.7 percent, which is a decrease of approximately $144.2 million to a decrease of approximately $119.7 million. In order to bring products into compliance with amended standards, it is estimated that industry will incur total conversion costs of $180.7 million.

DOE's analysis of the impacts of the adopted standards on manufacturers is described in section IV.J and section V.B.2 of this document.

C. National Benefits and Costs[9]

DOE's analyses indicate that the adopted energy conservation standards for consumer clothes dryers would save a significant amount of energy. Relative to the case without amended standards, the lifetime energy savings for consumer clothes dryers purchased in the 30-year period that begins in the anticipated year of compliance with the amended standards (2028–2057), amount to 2.7 quadrillion British thermal units (''Btu''), or quads.[10] This represents a savings of 11 percent relative to the energy use of these products in the case without amended standards (referred to as the ''no-new-standards case'').

The cumulative net present value (''NPV'') of total consumer benefits of the standards for consumer clothes dryers ranges from $ 9.23 billion (at a 7-percent discount rate) to $20.08 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product and installation costs for consumer clothes dryers purchased during the period 2028–2057.

In addition, the adopted standards for consumer clothes dryers are projected to yield significant environmental benefits. DOE estimates that the standards will result in cumulative emission reductions (over the same period as for

[6] The average LCC savings refer to consumers that are affected by a standard and are measured relative to the efficiency distribution in the no-new-standards case, which depicts the market in the compliance year in the absence of new or amended standards (*see* section IV.F.9 of this document). The simple PBP, which is designed to compare specific efficiency levels, is measured relative to the baseline product (*see* section IV.C of this document).

[7] DOE's analysis period extends 30 years from the compliance year. The analysis period for the MIA ranges from 2024–2056 for the no-new-standards case and all TSLs, except for TSL 3 (the Recommended TSL). The analysis period for the Recommended TSL ranges from 2024–2057 due to the 2028 compliance year.

[8] The no-new-standards case INPV of $2.12 billion reflects the sum of discounted free cash flows from 2024–2056 (from the reference year to 30 years after the 2027 compliance date) plus a discounted terminal value.

[9] All monetary values in this document are expressed in 2022 dollars and, where appropriate, are discounted to 2024 unless explicitly stated otherwise.

[10] The quantity refers to full-fuel-cycle (''FFC'') energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, *see* section IV.H.2 of this document.

energy savings) of 57.1 million metric tons (''Mt'') [11] of carbon dioxide (''CO_2''), 13.9 thousand tons of sulfur dioxide (''SO_2''), 116.5 thousand tons of nitrogen oxides (''NO_X''), 527.6 thousand tons of methane (''CH_4''), 0.5 thousand tons of nitrous oxide (''N_2O''), and 0.1 tons of mercury (''Hg'').[12] The estimated cumulative reduction in CO_2 emissions through 2030 amounts to 1.3 Mt, which is equivalent to the emissions resulting from the annual electricity use of more than 260 thousand homes.

DOE estimates the value of climate benefits from a reduction in greenhouse gases (''GHG'') using four different estimates of the social cost of CO_2 (''SC–CO_2''), the social cost of methane (''SC–CH_4''), and the social cost of nitrous oxide (''SC–N_2O''). Together these represent the social cost of GHG (''SC–GHG''). DOE used interim SC–GHG values (in terms of benefit per ton of GHG avoided) developed by an Interagency Working Group on the Social Cost of Greenhouse Gases (''IWG'').[13] The derivation of these values is discussed in section IV.L of this document. For presentational purposes, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are estimated to be $3.3 billion. DOE does not have a single central SC–GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates.

DOE estimated the monetary health benefits of SO_2 and NO_X emissions reductions, using benefit-per-ton estimates from the Environmental Protection Agency,[14] as discussed in section IV.L of this document. DOE estimated the present value of the health benefits would be $2.6 billion using a 7-percent discount rate, and $6.3 billion using a 3-percent discount rate.[15] DOE is currently only monetizing health benefits from changes in ambient fine particulate matter ($PM_{2.5}$) concentrations from two precursors (SO_2 and NO_X), and from changes in ambient ozone from one precursor (for NO_X), but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.

Table I.3 summarizes the monetized benefits and costs expected to result from the amended standards for consumer clothes dryers. There are other important unquantified effects, including certain unquantified climate benefits, unquantified public health benefits from the reduction of toxic air pollutants and other emissions, unquantified energy security benefits, and distributional effects, among others.

TABLE I.3—SUMMARY OF MONETIZED BENEFITS AND COSTS OF ADOPTED ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

	Billion (2022$)
3% discount rate	
Consumer Operating Cost Savings	21.1
Climate Benefits *	3.3
Health Benefits **	6.3
Total Benefits †	30.7
Consumer Incremental Product Costs ‡	1.0
Net Monetized Benefits	20.1
Change in Producer Cash Flow (INPV ‡‡)	(0.14)–(0.12)
7% discount rate	
Consumer Operating Cost Savings	9.8
Climate Benefits * (3% discount rate)	3.3
Health Benefits **	2.6
Total Benefits †	15.8
Consumer Incremental Product Costs ‡	0.6
Net Monetized Benefits	9.2
Change in Producer Cash Flow (INPV ‡‡)	(0.14)–(0.12)

Note: This table presents the costs and benefits associated with consumer clothes dryers shipped in 2028–2057. These results include consumer, climate, and health benefits that accrue after 2057 from the products shipped in 2028–2057.

* Climate benefits are calculated using four different estimates of the global SC–GHG (*see* section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown; however, DOE emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. *See* section IV.L of this document for more details.

† Total and net benefits include those consumer, climate, and health benefits that can be quantified and monetized. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with a 3-percent discount rate.

‡ Costs include incremental equipment costs as well as installation costs.

[11] A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO_2 are presented in short tons.

[12] DOE calculated emissions reductions relative to the no-new-standards case, which reflects key assumptions in the *Annual Energy Outlook 2023* (''*AEO2023*''). *AEO2023* represents current Federal and State legislation and final implementation of regulations as of the time of its preparation. *See* section IV.K of this document for further discussion of *AEO2023* assumptions that affect air pollutant emissions.

[13] To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG. (''February 2021 SC–GHG TSD''*). www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf.*

[14] U.S. EPA. Estimating the Benefit per Ton of Reducing Directly Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. Available at *www.epa.gov/benmap/estimating-benefit-ton-reducing-pm25-precursors-21-sectors.*

[15] DOE estimates the economic value of these emissions reductions resulting from the considered trial standard levels (''TSLs'') for the purpose of complying with the requirements of Executive Order 12866.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impact analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (the MIA). *See* section IV.J of this document and chapter 12 of the direct final rule technical support document ("TSD"). In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. Change in INPV is calculated using the industry weighted average cost of capital value of 7.5 percent that is estimated in the MIA (*see* chapter 12 of the direct final rule TSD for a complete description of the industry weighted average cost of capital). For consumer clothes dryers, those values are −$144 million to −$120 million. DOE accounts for that range of likely impacts in analyzing whether a TSL is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two manufacturer markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table, and the Preservation of Operating Profit scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated change in INPV in the above table, drawing on the MIA explained further in section IV.J of this document, to provide additional context for assessing the estimated impacts of this direct final rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the net benefit calculation for this direct final rule, the net benefits would range from $19.96 billion to $19.98 billion at 3-percent discount rate and would range from $9.06 billion to $9.08 billion at 7-percent discount rate. Parentheses ( ) indicate negative values.

The benefits and costs of the adopted standards can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are (1) the reduced consumer operating costs, minus (2) the increase in product purchase prices and installation costs, plus (3) the value of climate and health benefits of emission reductions, all annualized.[16]

The national operating cost savings are domestic private U.S. consumer monetary savings that occur as a result of purchasing the covered products and are measured for the lifetime of consumer clothes dryers shipped in 2028–2057. The benefits associated with reduced emissions achieved as a result of the adopted standards are also calculated based on the lifetime of consumer clothes dryers shipped in 2028–2057. Total benefits for both the 3-percent and 7-percent cases are presented using the average GHG social costs with a 3-percent discount rate. Estimates of SC–GHG values are presented for all four SC–GHG discount rates in section IV.L of this document.

Table I.4 presents the total estimated monetized benefits and costs associated with the adopted standards, expressed in terms of annualized values. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and health benefits from reduced NO_X and SO_2 emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated cost of the standards adopted in this rule is $60.0 million per year in increased equipment costs, while the estimated annual benefits are $971.4 million in reduced equipment operating costs, $185.5 million in climate benefits, and $259.9 million in health benefits. In this case, the net benefit would amount to $1,357 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the standards is $57.2 million per year in increased equipment costs, while the estimated annual benefits are $1,177 million in reduced operating costs, $185.5 million in climate benefits, and $349.4 million in health benefits. In this case, the net benefit would amount to $1,654 million per year.

TABLE I.4—ANNUALIZED BENEFITS AND COSTS OF ADOPTED STANDARDS FOR CONSUMER CLOTHES DRYERS (2028–2057)

	Million/year (2022$)		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	1,177	1,103	1,230
Climate Benefits *	185.5	178.9	187.8
Health Benefits **	349.4	337.2	353.7
Total Benefits †	1,712	1,619	1,771
Consumer Incremental Product Costs	57.2	58.9	54.4
Net Benefits	1,654	1,560	1,717
Change in Producer Cash Flow (INPV ‡‡)	(12)–(10)	(12)–(10)	(12)–(10)
7% discount rate			
Consumer Operating Cost Savings	971.4	915.5	1,014
Climate Benefits * (3% discount rate)	185.5	178.9	187.8
Health Benefits **	259.9	251.5	262.8
Total Benefits †	1,417	1,346	1,464
Consumer Incremental Product Costs ‡	60.0	61.2	57.7
Net Benefits	1,357	1,285	1,407

[16] To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2024, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (*e.g.,* 2020 or 2030), and then discounted the present value from each year to 2024. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year, that yields the same present value.

TABLE I.4—ANNUALIZED BENEFITS AND COSTS OF ADOPTED STANDARDS FOR CONSUMER CLOTHES DRYERS (2028–2057)—Continued

	Million/year (2022$)		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
Change in Producer Cash Flow (INPV ‡‡)	(12)–(10)	(12)–(10)	(12)–(10)

Note: This table presents the costs and benefits associated with consumer clothes dryers shipped in 2028–2057. These results include benefits to consumers which accrue after 2057 from the products shipped in 2028–2057. The Primary, Low-Net-Benefits, and High-Net-Benefits estimates utilize projections of energy prices from the *AEO2023* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a constant rate in the Low-Net-Benefits Estimate, and a high decline rate in the High-Net-Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.H.3 of this document. Note that the Benefits and Costs may not sum up to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC–GHG (*see* section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. *See* section IV.L of this document for more details.

† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with a 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate.

‡ Costs include incremental equipment costs as well as installation costs.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impact analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (the MIA). *See* section IV.J of this document and chapter 12 of the direct final rule TSD. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 7.5 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the direct final rule TSD for a complete description of the industry weighted average cost of capital). For consumer clothes dryers, those values are −$12 million to −$10 million. DOE accounts for that range of likely impacts in analyzing whether a TSL is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two manufacturer markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table, and the Preservation of Operating Profit Markup scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in chapter 12 of this direct final rule TSD, to provide additional context for assessing the estimated impacts of this direct final rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this direct final rule, the annualized net benefits, using the primary estimate, would range from $1,642 million to $1,644 at 3-percent discount rate and would range from $1,345 million to $1,347 million at 7-percent discount rate. Parentheses () indicate negative values.

DOE's analysis of the national impacts of the adopted standards is described in sections IV.H, IV.K, and IV.L of this document.

D. Conclusion

DOE has determined that the Joint Agreement was submitted jointly by interested persons that are fairly representative of relevant points of view, in accordance with 42 U.S.C. 6295(p)(4)(A). After considering the recommended standards and weighing the benefits and burdens, DOE has determined that the recommended standards are in accordance with 42 U.S.C. 6295(o), which contains the criteria for prescribing new or amended standards. Specifically, the Secretary of Energy (''Secretary'') has determined that the adoption of the recommended standards would result in the significant conservation of energy and is the maximum improvement in energy efficiency that is technologically feasible and economically justified. In determining whether the recommended standards are economically justified, the Secretary has determined that the benefits of the recommended standards exceed the burdens. The Secretary has further concluded that the recommended standards, when considering the benefits of energy savings, positive NPV of consumer benefits, emission reductions, the estimated monetary value of the emissions reductions, and positive average LCC savings, would yield benefits that outweigh the negative impacts on some consumers and on manufacturers, including the conversion costs that could result in a reduction in INPV for manufacturers.

Using a 7-percent discount rate for consumer benefits and costs and NO_X and SO_2 reduction benefits, and a 3-percent discount rate case for GHG social costs, the estimated cost of the standards for consumer clothes dryers is $60.0 million per year in increased product costs, while the estimated annual benefits are $971.4 million in reduced product operating costs, $185.5 million in climate benefits, and $259.9 million in health benefits. The net benefit amounts to $1,357 million per year. DOE notes that the net benefits are substantial even in the absence of the climate benefits,[17] and DOE would adopt the same standards in the absence of such benefits.

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[18] For example, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand.

[17] The information on climate benefits is provided in compliance with Executive Order 12866.

[18] Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment, 86 FR 70892, 70901 (Dec. 13, 2021).

The impacts of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis.

As previously mentioned, the standards are projected to result in estimated national energy savings of 2.7 quads FFC, the equivalent of the primary annual energy use of 18 million homes. In addition, they are projected to reduce cumulative CO_2 emissions by 57.1 Mt. Based on these findings, DOE has determined the energy savings from the standard levels adopted in this direct final rule are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B). A more detailed discussion of the basis for these conclusions is contained in the remainder of this document and the accompanying TSD.

Under the authority provided by 42 U.S.C. 6295(p)(4), DOE is issuing this direct final rule amending the energy conservation standards for consumer clothes dryers. Consistent with this authority, DOE is also simultaneously publishing elsewhere in this **Federal Register** a NOPR proposing standards that are identical to those contained in this direct final rule. *See* 42 U.S.C. 6295(p)(4)(A)(i).

II. Introduction

The following section briefly discusses the statutory authority underlying this direct final rule, as well as some of the relevant historical background related to the establishment of standards for consumer clothes dryers.

A. Authority

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include consumer clothes dryers, the subject of this document. (42 U.S.C. 6292(a)(8)) EPCA prescribed energy conservation standards for these products (42 U.S.C. 6295(g)(3)), and directed DOE to conduct future rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(g)(4)) EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions set forth under EPCA. (42 U.S.C. 6297(d))

Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and 42 U.S.C. 6295(r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for consumer clothes dryers appear at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix D1 (''appendix D1'') and appendix D2 (''appendix D2'').

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including consumer clothes dryers. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

Moreover, DOE may not prescribe a standard if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(3)(B)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA, as codified, also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of evidence that the standard is likely to result in the unavailability in the United States in

any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. A rule prescribing an energy conservation standard for a type (or class) of product must specify a different standard level for a type or class of products that has the same function or intended use if DOE determines that products within such group (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE consider such factors as the utility to the consumer of such a feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Additionally, pursuant to the amendments contained in the Energy Independence and Security Act of 2007 (''EISA 2007''), Public Law 110–140, final rules for new or amended energy conservation standards promulgated after July 1, 2010, are required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedures for consumer clothes dryers address standby mode and off mode energy use, as do the amended standards adopted in this direct final rule.

Finally, EISA 2007 amended EPCA, in relevant part, to grant DOE authority to directly issue a final rule (*i.e.,* a ''direct final rule'') establishing an energy conservation standard upon receipt of a statement submitted jointly by interested persons that are fairly representative of relevant points of view (including representatives of manufacturers of covered products, States, and efficiency advocates), as determined by the Secretary, that contains recommendations with respect to an energy or water conservation standard. (42 U.S.C. 6295(p)(4)) Pursuant to 42 U.S.C. 6295(p)(4), the Secretary must also determine whether a jointly submitted recommendation for an energy or water conservation standard satisfies 42 U.S.C. 6295(o) or 42 U.S.C. 6313(a)(6)(B), as applicable.

The direct final rule must be published simultaneously with a NOPR that proposes an energy or water conservation standard that is identical to the standard established in the direct final rule, and DOE must provide a public comment period of at least 110 days on this proposal. (42 U.S.C. 6295(p)(4)(A)–(B)) While DOE typically provides a comment period of 60 days on proposed standards, for a NOPR accompanying a direct final rule, DOE provides a comment period of the same length as the comment period on the direct final rule—*i.e.,* 110 days. Based on the comments received during this period, the direct final rule will either become effective, or DOE will withdraw it not later than 120 days after its issuance if: (1) one or more adverse comments is received, and (2) DOE determines that those comments, when viewed in light of the rulemaking record related to the direct final rule, may provide a reasonable basis for withdrawal of the direct final rule under 42 U.S.C. 6295(o). (42 U.S.C. 6295(p)(4)(C)) Receipt of an alternative joint recommendation may also trigger a DOE withdrawal of the direct final rule in the same manner. (*Id.*)

DOE has previously explained its interpretation of its direct final rule authority. In a final rule amending the Department's ''Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products'' at 10 CFR part 430, subpart C, appendix A (''Process Rule'' or ''appendix A''), DOE noted that it may issue standards recommended by interested persons that are fairly representative of relative points of view as a direct final rule when the recommended standards are in accordance with 42 U.S.C. 6295(o) or 42 U.S.C. 6313(a)(6)(B), as applicable. 86 FR 70892, 70912 (Dec. 13, 2021). But the direct final rule provision in EPCA does not impose additional requirements applicable to other standards rulemakings, which is consistent with the unique circumstances of rules issued through consensus agreements under DOE's direct final rule authority. *Id.* DOE's discretion remains bounded by its statutory mandate to adopt a standard that results in the maximum improvement in energy efficiency that is technologically feasible and economically justified—a requirement found in 42 U.S.C. 6295(o). *Id.* As such, DOE's review and analysis of the Joint Agreement is limited to whether the recommended standards satisfy the criteria in 42 U.S.C. 6295(o).

B. Background

1. Current Standards

In a direct final rule published on April 21, 2011, (''April 2011 Direct Final Rule'') DOE prescribed the current energy conservation standards for consumer clothes dryers manufactured on and after January 1, 2015. 76 FR 22454.[19] These standards are set forth in DOE's regulations at 10 CFR 430.32(h)(3) and are shown in Table II.1. These standards are consistent with a prior joint proposal submitted to DOE by interested parties representing manufacturers, energy and environmental advocates, and consumer groups.[20]

The current standards are defined in terms of a minimum allowable CEF, as measured according to appendix D1. Even though DOE maintained the same energy efficiency descriptor for both appendix D1 and appendix D2, DOE notes that the CEF values are not equivalent because of the extensive differences in test methods.[21] To avoid potential confusion that would result from using the same efficiency descriptor for both test procedures as it relates to the standards discussed in this document, DOE is including a ''D1'' or ''D2'' subscript when referring to the appendix D1 CEF and appendix D2 CEF, respectively (''CEF_{D1}'' and ''CEF_{D2}'').

[19] DOE published a confirmation of effective date and compliance date for the direct final rule on August 24, 2011. 76 FR 52854.

[20] Available at: *www.regulations.gov/comment/EERE-2007-BT-STD-0010-0049.*

[21] While the current standards are based on CEF as determined in accordance with appendix D1, manufacturers are permitted to use the appendix D2 test procedure to comply with the current standards, as long as they use a single appendix for all representations. Beginning on the compliance date of the amended standards established by this direct final rule, manufacturers will be required to use appendix D2 to comply with the amended standards.

TABLE II.1—FEDERAL ENERGY EFFICIENCY STANDARDS FOR CONSUMER CLOTHES DRYERS AS MEASURED UNDER APPENDIX D1

Product class	CEF_{D1} *(lb/kWh)*
(i) Vented Electric, Standard (4.4 ft^3 or greater capacity)	3.73
(ii) Vented Electric, Compact (120V) (less than 4.4 ft^3 capacity)	3.61
(iii) Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	3.27
(iv) Vented Gas	3.30
(v) Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	2.55
(vi) Ventless Electric, Combination Washer-Dryer	2.08

2. Current Test Procedure

On October 8, 2021, DOE published a final rule for the test procedure rulemaking (86 FR 56608) (the ''October 2021 TP Final Rule''), in which it amended appendix D1 and appendix D2, both entitled ''Uniform Test Method for Measuring the Energy Consumption of Clothes Dryers,'' to provide additional detail in response to questions from manufacturers and test laboratories, including additional detail regarding the testing of ''connected'' models, dryness level selection, and the procedures for maintaining the required heat input rate for gas consumer clothes dryers; additional detail for the test procedures for performing inactive and off mode power measurements; specifications for the final moisture content (''FMC'') required for testing automatic termination control dryers; specification of a narrower scale resolution for the weighing scale used to determine moisture content of test loads; and specification that the test load must be weighed within 5 minutes after a test cycle has terminated. In addition, as part of the October 2021 TP Final Rule, DOE amended the test procedures to update the estimated number of annual use cycles for consumer clothes dryers; provide further direction for additional provisions within the test procedures; specify rounding requirements for all reported values; apply consistent use of nomenclature and correct typographical errors; remove obsolete sections of the test procedures, including appendix D; and update the reference to the applicable industry test procedure to the version certified by the American National Standards Institute (''ANSI''). 86 FR 56608, 56610.

DOE's current energy conservation standards for consumer clothes dryers are expressed in terms of CEF_{D1}. (*See* 10 CFR 430.32(h)(3).) Appendix D1 tests timed drying cycles, and accounts for clothes dryers with automatic termination controls by applying a higher field use factor to units that have this feature. Appendix D2 tests ''normal'' automatic termination cycles and more accurately measures the effects of automatic cycle termination.

EPCA authorizes DOE to design test procedures that measure energy efficiency, energy use, water use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(3)) The appendix D2 test procedure, which is required for use to demonstrate compliance with the amended energy conservation standards established in this direct final rule, measures the energy consumption of a representative use cycle that dries a load of laundry from an initial moisture content of 57.5 percent to an FMC of less than 2 percent. 86 FR 56624–56625. For timer clothes dryers, the test load is dried until the FMC is between 1 and 2.5 percent of the bone-dry weight of the test load. The measured energy consumption is then normalized to determine the energy consumption required to dry the test load to 2-percent FMC, with a field use factor applied to account for the over-drying energy consumption. For automatic termination control clothes dryers, appendix D2 specifies that a ''normal'' program be selected for the test cycle, and for clothes dryers that do not have a ''normal'' program, the cycle recommended by the manufacturer for drying cotton or linen shall be selected. If the drying temperature and drying level settings can be chosen independently of the program, they shall be set at the maximum drying temperature setting, and at a ''normal'' or ''medium'' dryness level setting. The test is considered valid if the FMC of the test load is 2 percent or less after the completion of the test cycle. If the FMC is greater than 2 percent, the test is considered invalid and a new run shall be conducted using the highest dryness level setting.

The current 2-percent FMC requirement using the DOE test cloth was adopted as representative of approximately 5-percent FMC for ''real-world'' clothing, based on data submitted in a joint petition for rulemaking.[22] DOE determined in the final rule published on August 14, 2013, that established the appendix D2 Test procedure that the specified 2-percent FMC using the DOE test load was representative of consumer expectations for dryness of clothing in field use. 78 FR 49608, 49620–49622, 49610–49611. DOE did not amend the FMC requirements in the October 2021 TP Final Rule. 86 FR 56626.

DOE has conducted the rulemaking analysis for this direct final rule based on CEF_{D2} because compliance with the amended energy conservation standards established in this direct final rule must be determined based on the use of appendix D2. DOE discusses additional details in section IV.C.1 of this document about how it developed the engineering baseline, in terms of CEF_{D2}, from the current consumer clothes dryer standards that are in terms of CEF_{D1}.

3. The Joint Agreement

On September 25, 2023, DOE received a joint statement of recommended standards (*i.e.,* the Joint Agreement) for various home appliance products, including consumer clothes dryers, submitted jointly by groups representing manufacturers, energy and environmental advocates, consumer groups, and a utility.[23] In addition to the

[22] The petition was submitted by AHAM, Whirlpool Corporation, General Electric Company, Electrolux, LG Electronics, Inc., BSH, Alliance Laundry Systems, Viking Range, Sub-Zero Wolf, Friedrich A/C, U-Line, Samsung, Sharp Electronics, Miele, Heat Controller, AGA Marvel, Brown Stove, Haier, Fagor America, Airwell Group, Arcelik, Fisher & Paykel, Scotsman Ice, Indesit, Kuppersbusch, Kelon, and DeLonghi, American Council for an Energy Efficient Economy, Appliance Standards Awareness Project, Natural Resources Defense Council, Alliance to Save Energy, Alliance for Water Efficiency, Northwest Power and Conservation Council, and Northeast Energy Efficiency Partnerships, Consumer Federation of America and the National Consumer Law Center. See Docket No. EERE–2011–BT–TP–0054, No. 3.

[23] The signatories to the Joint Agreement include AHAM, American Council for an Energy-Efficient Economy, Alliance for Water Efficiency, Appliance Standards Awareness Project, Consumer Federation of America, Consumer Reports, Earthjustice, National Consumer Law Center, Natural Resources Defense Council, Northwest Energy Efficiency

recommended standards for consumer clothes dryers, the Joint Agreement also included separate recommendations for several other covered products.[24] And, while acknowledging that DOE may implement these recommendations in separate rulemakings, the Joint Agreement also stated that the recommendations were recommended as a complete package and each recommendation is contingent upon the other parts being implemented. DOE understands this to mean that the Joint Agreement is contingent upon DOE initiating rulemaking processes to adopt all of the recommended standards in the agreement. That is distinguished from an agreement where issuance of an amended energy conservation standard for a covered product is contingent on issuance of amended energy conservation standards for the other covered products. If the Joint Agreement were so construed, it would conflict with the anti-backsliding provision in 42 U.S.C. 6295(o)(1), because it would imply the possibility that, if DOE were unable to issue an amended standard for a certain product, it would have to withdraw a previously issued standard for one of the other products. The anti-backsliding provision, however, prevents DOE from withdrawing or amending an energy conservation standard to be less stringent. As a result, DOE will be proceeding with individual rulemakings that will evaluate each of the recommended standards separately under the applicable statutory criteria.

A court decision issued after DOE received the Joint Agreement is also relevant to this rule. On March 17, 2022, various States filed a petition seeking review of a final rule revoking two final rules that established product classes for residential dishwashers with a cycle time for the normal cycle of 60 minutes or less, top-loading residential clothes washers (''RCWs'') and certain classes of consumer clothes dryers with a cycle time of less than 30 minutes, and front-loading RCWs with a cycle time of less than 45 minutes (collectively, ''short cycle product classes''). The petitioners argued that the final rule revoking the short cycle product classes violated EPCA and was arbitrary and capricious. On January 8, 2024, the United States Court of Appeals for the Fifth Circuit granted the petition for review and remanded the matter to DOE for further proceedings consistent with the Fifth Circuit's opinion. *See Louisiana* v. *United States Department of Energy,* 90 F.4th 461 (5th Cir. 2024). On February 14, 2024, following the Fifth Circuit's decision in *Louisiana* v. *United States Department of Energy,* DOE received a second joint statement from this same group of stakeholders in which the signatories reaffirmed the Joint Agreement, stating that the recommended standards represent the maximum levels of efficiency that are technologically feasible and economically justified.[25] In the letter, the signatories clarified that ''short-cycle'' product classes for RCWs, clothes dryers, and dishwashers did not exist at the time that the signatories submitted their recommendations and it is their understanding that these classes also do not exist at the current time. Accordingly, the parties clarified that the Joint Agreement did not address short-cycle product classes. The signatories also stated that they did not anticipate that the recommended energy conservation standards in the Joint Agreement will negatively affect features or performance, including cycle time, for consumer clothes dryers.

The Joint Agreement recommends amended standard levels for consumer clothes dryers as presented in Table II.2. (Joint Agreement, No. 55 at p. 9) [26] Details of the Joint Agreement recommendations for other products are provided in the Joint Agreement posted in the docket.[27]

TABLE II.2—RECOMMENDED AMENDED ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

Product class	Minimum energy efficiency ratio (lb/kWh)	Compliance date
Electric, Standard (4.4 cubic feet (''ft^3'') or greater capacity)	*3.93*	March 1, 2028
Electric, Compact (120 volts (''V'')) (less than 4.4 ft^3 capacity)	*4.33*	
Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	*3.57*	
Vented Gas, Standard (4.4 ft^3 or greater capacity)	*3.48*	
Vented Gas, Compact (less than 4.4 ft^3 capacity)	*2.02*	
Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	*2.68*	
Ventless Electric, Combination Washer-Dryer	*2.33*	

When the Joint Agreement was submitted, DOE was conducting a rulemaking to consider amending the standards for consumer clothes dryers. As part of that process, DOE published a NOPR and announced a public meeting on August 23, 2022 (''August 2022 NOPR'') seeking comment on its proposed amended standard to inform its decision consistent with its obligations under EPCA and the Administrative Procedure Act (''APA''). 87 FR 51734. DOE subsequently held a public webinar on September 13, 2022, to discuss and receive comments on the NOPR TSD.

Although DOE is adopting the Joint Agreement as a direct final rule and no

Alliance, and Pacific Gas and Electric Company. Members of AHAM's Major Appliance Division that make the affected products include: Alliance Laundry Systems, LLC; Asko Appliances AB; Beko US Inc.; Brown Stove Works, Inc.; BSH Home Appliances Corporation; Danby Products, Ltd.; Electrolux Home Products, Inc.,; Elicamex S.A. de C.V.; Faber; Fotile America; GE Appliances, a Haier Company; L'Atelier Paris Haute Design LLG; LG Electronics; Liebherr USA, Co.; Midea America Corp.; Miele, Inc.; Panasonic Appliances Refrigeration Systems (PAPRSA) Corporation of America; Perlick Corporation; Samsung Electronics America Inc; Sharp Electronics Corporation; Smeg S.p.A; Sub-Zero Group, Inc.; The Middleby Corporation; U-Line Corporation; Viking Range, LLC; and Whirlpool Corporation.

[24] The Joint Agreement contained recommendations for 6 covered products: refrigerators, refrigerator-freezers, and freezers; clothes washers; clothes dryers; dishwashers; cooking products; and miscellaneous refrigeration products.

[25] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058*.

[26] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop energy conservation standards for consumer clothes dryers. (Docket No. EERE–2014–BT–STD–0058, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number at page of that document).

[27] The Joint Agreement available in the docket at *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0055*.

longer proceeding with its prior rulemaking, DOE did consider relevant comments, data, and information obtained during that rulemaking process in determining whether the recommended standards from the Joint Agreement are in accordance with 42 U.S.C. 6295(o). Any discussion of comments, data, or information in this direct final rule that were obtained during DOE's prior rulemaking will include a parenthetical reference that provides the location of the item in the public record.[28]

III. General Discussion

DOE is issuing this direct final rule after determining that the recommended standards submitted in the Joint Agreement meet the requirements in 42 U.S.C. 6295(p)(4). More specifically, DOE has determined that the recommended standards were submitted by interested persons that are fairly representative of relevant points of view and the recommended standards satisfy the criteria in 42 U.S.C. 6295(o).

On March 17, 2022, various states filed a petition seeking review of a final rule revoking two final rules that established product classes for residential dishwashers with a cycle time for the normal cycle of 60 minutes or less, top-loading RCWs and certain classes of consumer clothes dryers with a cycle time of less than 30 minutes, and front-loading RCWs with a cycle time of less than 45 minutes (collectively, ''short cycle product classes''). The petitioners argued that the final rule revoking the short cycle product classes violated EPCA and was arbitrary and capricious. On January 8, 2024, the United States Court of Appeals for the Fifth Circuit granted the petition for review and remanded the matter to DOE for further proceedings consistent with the Fifth Circuit's opinion. *See Louisiana* v. *United States Department of Energy,* 90 F.4th 461 (5th Cir. 2024)

Following the Fifth Circuit's decision, the signatories to the Joint Agreement submitted a second letter to DOE, which stated that Joint Recommendation did not ''address'' ''short-cycle product classes.'' [29] That is because, as the letter explained, such product classes ''did not exist'' at the time of the Joint Agreement.

In a recently issued Request for Information,[30] DOE is commencing a rulemaking process on remand from the Fifth Circuit (the Remand Proceeding) by soliciting further information, relevant to the issues identified by the Fifth Circuit, regarding any short cycle product classes. In that Remand Proceeding, DOE will conduct the analysis required by 42 U.S.C. 6295(q)(1)(B) to determine whether any short-cycle products have a ''capacity or other performance-related feature [that] . . . justifies a higher or lower standard from that which applies (or will apply) to other products. . . .''

The current standards applicable to any products within the scope of that proceeding remain unchanged by this rule. *See* 10 CFR 430.32(g). Consistent with the Joint Parties' letter, short-cycle products are not subject to the amended standards adopted by this direct final rule. If the short-cycle products that DOE will consider in the Remand Proceeding were subject to these standards, that would have the practical effect of limiting the options available in the Remand Proceeding. That is because EPCA's anti-backsliding provision precludes DOE from prescribing any amended standard ''which increases the maximum allowable energy use'' of a covered product. 42 U.S.C. 6295(o)(1). Accordingly, were the products at issue in the Remand Proceeding also subject to the amended standards adopted here, the Department could only reaffirm the standards adopted in this direct final rule or adopt more stringent standards.

The Joint Agreement specifies the product classes for consumer clothes dryers: electric, standard; electric, compact; vented electric, compact; vented gas, standard; vented gas, compact; ventless electric, compact; and ventless electric, combination washer-dryer. Although these product classes were not further divided by cycle time, DOE understands them to exclude vented electric standard-size clothes dryers and vented gas standard-size clothes dryers with a cycle time of less than 30 minutes, when tested according to appendix D2. As previously noted, any such ''short-cycle'' consumer clothes dryers will be considered in the Remand Proceeding; the current standards applicable to such ''short-cycle'' consumer clothes dryers are unchanged by this rule.

Under the direct final rule authority at 42 U.S.C. 6295(p)(4), DOE evaluates whether recommended standards are in accordance with criteria contained in 42 U.S.C. 6295(o). DOE does not have the authority to revise recommended standards submitted under the direct final rule provision in EPCA. Therefore, DOE did not analyze any additional product classes beyond those product classes included in the Joint Agreement. That is, DOE has not separately considered or established amended standards applicable to any short-cycle product classes. In the event that DOE establishes short-cycle product classes, pursuant to the rulemaking on remand from the Fifth Circuit, DOE will necessarily consider what amended standards ought to apply to any such product classes and will do so in conformance with EPCA.

DOE notes that the data and analysis used to support this direct final rule includes information for vented electric standard-size clothes dryers and vented gas standard-size clothes dryers that is not distinguished by cycle time and is representative of all consumer clothes dryers currently on the market today. To the extent that any short cycle product classes were included in this data and analysis, DOE believes the amount of such data is negligible.

A. Scope of Coverage

Before discussing how the Joint Agreement meets the requirements for issuing a direct final rule, it is important to clarify the scope of coverage for the recommended standards. EPCA does not define the term ''clothes dryer.'' (*See* 42 U.S.C. 6291) DOE has defined an ''electric clothes dryer'' as a cabinet-like appliance designed to dry fabrics in a tumble-type drum with forced air circulation. The heat source is electricity and the drum and blower(s) are driven by an electric motor(s). 10 CFR 430.2. DOE has defined a ''gas clothes dryer'' as a cabinet-like appliance designed to dry fabrics in a tumble-type drum with forced air circulation. The heat source is gas and the drum and blower(s) are driven by an electric motor(s). *Id.* This direct final rule covers consumer clothes dryers, *i.e.,* those consumer products that meet the definitions of ''electric clothes dryer'' and ''gas clothes dryer,'' as codified at 10 CFR 430.2.

See section IV.A.1 of this document for discussion of the product classes analyzed in this direct final rule.

B. Fairly Representative of Relevant Points of View

Under the direct final rule provision in EPCA, recommended energy conservation standards must be submitted by interested persons that are fairly representative of relevant points

[28] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop energy conservation standards for consumer clothes dryers. (Docket No. EERE–2014–BT–STD–0058, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number at page of that document).

[29] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058.*

[30] See *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=50.*

of view (including representatives of manufacturers of covered products, States, and efficiency advocates) as determined by DOE. (42 U.S.C. 6295(p)(4)(A)) With respect to this requirement, DOE notes that the Joint Agreement included a trade association, AHAM, which represents 11 manufacturers of consumer clothes dryers.[31] The Joint Agreement also included environmental and energy-efficiency advocacy organizations, consumer advocacy organizations, and a gas and electric utility company. Additionally, DOE received a letter in support of the Joint Agreement from the States of New York, California, and Massachusetts (*See* comment No. 56). DOE also received a letter in support of the Joint Agreement from a gas and electric utility, SDG&E, and an electric utility, SCE (*See* comment No. 57). As a result, DOE has determined that the Joint Agreement was submitted by interested persons who are fairly representative of relevant points of view.

C. Technological Feasibility

1. General

In each energy conservation standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. In evaluating the recommended standards proposed in the Joint Agreement, DOE conducted the same analysis. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible. Sections 6(b)(3)(i) and 7(b)(1) of appendix A.

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; (3) adverse impacts on health or safety; and (4) unique-pathway proprietary technologies. Sections 7(b)(2)–(5) of appendix A. Section IV.B of this document discusses the results of the screening analysis for consumer clothes dryers, particularly the designs DOE considered, those it screened out, and those that are the basis for the standards considered in this rulemaking. For further details on the screening analysis for this rulemaking, *see* chapter 4 of the direct final rule TSD.

2. Maximum Technologically Feasible Levels

When DOE proposes to adopt an amended standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(o)(2)(A)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in energy efficiency for consumer clothes dryers using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this rulemaking are described in section IV.C of this document and in chapter 5 of the direct final rule TSD.

D. Energy Savings

1. Determination of Savings

For each TSL considered, DOE projected energy savings from application of the TSL to consumer clothes dryers purchased in the 30-year period that begins in the year of compliance with the amended standards (2027–2056 for all TSLs except the Recommended TSL (*i.e.,* TSL 3) and 2028–2057 for TSL 3).[32] The savings are measured over the entire lifetime of consumer clothes dryers purchased in the 30-year analysis period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the no-new-standards case. The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards.

DOE used its national impact analysis (''NIA'') spreadsheet models to estimate national energy savings (''NES'') from potential amended standards for consumer clothes dryers. The NIA spreadsheet model (described in section IV.H of this document) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports national energy savings in terms of primary energy savings, which is the savings in the energy that is used to generate and transmit the site electricity. For natural gas, the primary energy savings are considered to be equal to the site energy savings. DOE also calculates NES in terms of FFC energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.[33] DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, *see* section IV.H.2 of this document.

2. Significance of Savings

To adopt any new or amended standards for a covered product including through a direct final rule, DOE must determine that such action would result in significant energy savings. (42 U.S.C. 6295(o)(3)(B))

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[34] For example, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand. The impact of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis, taking into account the significance of cumulative FFC national energy savings, the cumulative FFC emissions reductions, and the need to confront the global climate crisis, among other factors.

As stated, the standard levels adopted in this direct final rule are projected to result in national energy savings of 2.7 quads, the equivalent of the electricity

[31] These companies include: Alliance Laundry Systems, LLC; Beko US Inc.; BSH Home Appliances Corporation; Danby Products, Ltd.; Electrolux Home Products, Inc.; GE Appliances, a Haier Company; LG Electronics; Midea America Corp.; Miele, Inc.; Samsung Electronics America Inc.; and Whirlpool Corporation.

[32] DOE also presents a sensitivity analysis that considers impacts for products shipped in a 9-year period.

[33] The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

[34] Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment, 86 FR 70892, 70901 (Dec. 13, 2021).

use of 18 million homes in one year. Based on the amount of FFC savings, the corresponding reduction in emissions, and the need to confront the global climate crisis, DOE has determined the energy savings from the standard levels adopted in this direct final rule are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B).

E. Economic Justification

1. Specific Criteria

As noted previously, EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(I)(VII)) The following sections discuss how DOE has addressed each of those seven factors in this direct final rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of amended standards on manufacturers, DOE conducts an MIA, as discussed in section IV.J of this document. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include (1) INPV, which values the industry on the basis of expected future cash flows; (2) cash flows by year; (3) changes in revenue and income; and (4) other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and PBP associated with new or amended standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the consumer costs and benefits expected to result from particular standards. DOE also evaluates the impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a standard.

b. Savings in Operating Costs Compared to Increase in Price (LCC and PBP)

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered product that are likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating cost (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with new or amended standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of new or amended standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F of this document.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section IV.H of this document, DOE uses the NIA spreadsheet models to project national energy savings.

d. Lessening of Utility or Performance of Products

In evaluating design options and the impact of the recommended standard levels, DOE evaluates potential standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards adopted in this document would not reduce the utility or performance of the products under consideration in this rulemaking.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) DOE will transmit a copy of this direct final rule to the Attorney General with a request that the Department of Justice (''DOJ'') provide its determination on this issue. DOE will consider DOJ's comments on the rule in determining whether to withdraw the direct final rule. DOE will also publish and respond to the DOJ's comments in the **Federal Register** in a separate document.

f. Need for National Energy Conservation

DOE also considers the need for national energy and water conservation in determining whether a new or amended standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(VI)) The energy savings from the adopted standards are likely to provide improvements to the security and reliability of the Nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the Nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the Nation's needed power generation capacity, as discussed in section IV.M of this document.

DOE maintains that environmental and public health benefits associated with the more efficient use of energy are important to take into account when

considering the need for national energy conservation. The adopted standards are likely to result in environmental benefits in the form of reduced emissions of air pollutants and GHGs associated with energy production and use. DOE conducts an emissions analysis to estimate how potential standards may affect these emissions, as discussed in section IV.K of this document; the estimated emissions impacts are reported in section V.B.6 of this document. DOE also estimates the economic value of emissions reductions resulting from the considered TSLs, as discussed in section IV.L of this document.

g. Other Factors

In determining whether an energy conservation standard is economically justified, DOE may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) To the extent DOE identifies any relevant information regarding economic justification that does not fit into the other categories described previously, DOE could consider such information under ''other factors.''

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effect potential amended energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the Nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in section IV.F of this document.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this rulemaking regarding consumer clothes dryers. Separate subsections address each component of DOE's analyses, including relevant comments DOE received during its separate rulemaking to amend the energy conservation standards for consumer clothes dryers prior to receiving the Joint Agreement.

DOE used several analytical tools to estimate the impact of the standards considered in this document. The first tool is a spreadsheet that calculates the LCC savings and PBP of potential amended or new energy conservation standards. The national impacts analysis uses a second spreadsheet set that provides shipments projections and calculates national energy savings and net present value of total consumer costs and savings expected to result from potential energy conservation standards. DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (''GRIM''), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available on the DOE website for this rulemaking: *www.regulations.gov/docket/EERE-2014-BT-STD-0058*. Additionally, DOE used output from the latest version of the Energy Information Administration's (''EIA's'') *Annual Energy Outlook 2023* (''*AEO2023*'') for the emissions and utility impact analyses.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment for this rulemaking include (1) a determination of the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of consumer clothes dryers. The key findings of DOE's market assessment are summarized in the following sections. *See* chapter 3 of the direct final rule TSD for further discussion of the market and technology assessment.

1. Product Classes

The Joint Agreement specifies seven product classes for consumer clothes dryers. (Joint Agreement, No. 55 at p. 9). In this direct final rule, DOE is adopting the product classes from the Joint Agreement, as listed in Table IV.1.

TABLE IV.1—JOINT AGREEMENT CONSUMER CLOTHES DRYER PRODUCT CLASSES

Product classes
1. Electric, Standard (4.4 ft3 or greater capacity)
2. Electric, Compact (120V) (less than 4.4 ft3 capacity)
3. Vented Electric, Compact (240V) (less than 4.4 ft3 capacity)
4. Vented Gas, Standard (4.4 ft3 or greater capacity)
5. Vented Gas, Compact (less than 4.4 ft3 capacity)
6. Ventless Electric, Compact (240V) (less than 4.4 ft3 capacity)
7. Ventless Electric, Combination Washer-Dryer

DOE further notes that product classes established through EPCA's direct final rule authority are not subject to the criteria specified at 42 U.S.C. 6295(q)(1) for establishing product classes. However, in accordance with 42 U.S.C. 6295(o)(4)—which is applicable to direct final rules—DOE has concluded that the standards adopted in this direct final rule will not result in the unavailability in any covered product type (or class) of performance characteristics, features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States currently.[35] Additionally, DOE notes that DOE's findings in this regard are discussed in detail in section V.B.4 of this document.

2. Technology Options

In this direct final rule, DOE considered the technology options listed in Table IV.2, consistent with the table of technology options presented in the August 2022 NOPR. 87 FR 51734. Chapter 3 of the TSD for this direct final

[35] EPCA specifies that DOE may not prescribe an amended or new standard if the Secretary finds (and publishes such finding) that interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding. (42 U.S.C. 6295(o)(4))

rule includes a detailed list and descriptions of all technology options identified for consumer clothes dryers. As discussed in chapter 3 of the TSD for this direct final rule, DOE has performed market research and evaluated available consumer clothes dryers to assess existing technology options to improve efficiency. The results of this research are discussed in chapter 3 of the TSD for this direct final rule. DOE notes that it did not receive any comments regarding the technology options analyzed in the August 2022 NOPR.

TABLE IV.2—DIRECT FINAL RULE ANALYSIS: TECHNOLOGY OPTIONS FOR CONSUMER CLOTHES DRYERS

Dryer control or drum upgrades:
Improved termination
Increased insulation
Modified operating conditions
Improved air circulation
Improved drum design
Methods of Exhaust Heat Recovery (Vented Models Only):
Recycle exhaust heat
Inlet air preheat
Inlet air preheat, condensing mode
Moisture Removal Options:
Heat pump, electric only
Thermoelectric heating, electric only
Microwave, electric only
Modulating heat
Indirect heating
RF drying, electric only
Ultrasonic drying, electric only
Component Improvements:
Improved motor efficiency
Improved fan efficiency
Standby Power Improvements:
Transformerless power supply with auto-powerdown

B. Screening Analysis

DOE uses the following screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in commercially viable, existing prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility.* If a technology is determined to have a significant adverse impact on the utility of the product to subgroups of consumers or result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Safety of technologies.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-pathway proprietary technologies.* If a technology has proprietary protection and represents a unique pathway to achieving a given efficiency level, it will not be considered further, due to the potential for monopolistic concerns.

10 CFR part 430, subpart C, appendix A, sections 6(b)(3) and 7(b).

In sum, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed five criteria, it will be excluded from further consideration in the engineering analysis. The reasons for eliminating any technology are discussed in the following sections.

The subsequent sections include DOE's evaluation of each technology option against the screening analysis criteria, and whether DOE determined that a technology option should be excluded (''screened out'') based on the screening criteria.

1. Screened Out Technologies

In conducting the screening analysis for this direct final rule, DOE considered comments it had received in response to the screening analysis conducted for the August 2022 NOPR.

a. Thermoelectric Heating, Electric Only

DOE notes that thermoelectric heating clothes dryers are still undergoing preliminary research, including at Oak Ridge National Laboratory (''ORNL''). While ORNL's test results of a preliminary prototype have shown the potential for improved efficiency, ORNL indicated that the initial prototype design produced longer-than-desired drying times due to direct-contact heat transfer limitations via the drum surface. ORNL subsequently developed another prototype that added pumped secondary water loops that transferred heat from the thermoelectric modules to the process air via air-to-water heat exchangers to further improve efficiency and minimize cycle length. ORNL's testing indicated efficiency and cycle times for this prototype that are approximately equivalent to those of vapor compression heat pump clothes dryers.[36] Because the research for such a thermoelectric heating clothes dryer that produces energy savings and meets consumer expectations for drying cycle time is still in the prototype stage, DOE determined that this technology option would not be practicable to manufacture, install, and service on a scale necessary to serve the relevant market at the time of the projected compliance date of any new or amended consumer clothes dryer standards, and did not consider it for further analysis.

[36] Patel, V., Boudreaux, P., and Gluesenkamp, K. Oak Ridge National Laboratory. Validated Model of a Thermoelectric Heat Pump Clothes Dryer Using Secondary Pumped Loops. Applied Thermal Engineering, Volume 184, February 5, 2021.

b. Microwave, Electric Only

Due to the large energy savings associated with microwave drying, this technology was the subject of a multiyear development effort at the Electric Power Research Institute (''EPRI'') in the mid-1990s.[37] At least one major manufacturer—Whirlpool—developed a countertop-scale version of such a product as recently as 2002,[38] but to date this technology has not been successfully commercialized.

Microwave drying introduces significant technical and safety issues with potential arcing from metallic objects in the fabric load, including zippers, buttons, or ''stray'' items such as coins. While efforts have been made to mitigate the conditions that are favorable to arcing or to detect incipient arcing and terminate the cycle, the possibility of fabric damage cannot be completely eliminated.[39] In addition to those consumer utility impacts, these conditions can also pose a safety hazard. For these reasons, microwave drying was not considered further for analysis.

c. Indirect Heating

Indirect heating would be viable only in residences that use a hydronic heating system. Also, in order to derive clothes dryer heat energy from a home's heating system, significant plumbing work would be required to circulate heated water through a heat exchanger in the clothes dryer. Therefore, this technology option does not meet the criterion of practicability to install on a scale necessary to serve the relevant market at the time of the effective date of any new standard and was not considered for further analysis.

d. RF Drying, Electric Only

CoolDry, LLC (''CoolDry'') developed an RF clothes dryer prototype, claiming an efficiency of 90 percent, compared to 50 percent for conventional clothes dryers.[40] CoolDry stated that its RF drying technology operates at lower temperatures than do conventional clothes dryers and, because the transfer of energy to clothes is not dependent on convective heat transfer, the RF clothes dryer requires less tumbling and subsequently consumes less energy for drum rotation than a conventional clothes dryer. Because this technology was in the prototype stage at the time it was initially considered and the company is no longer in business, research and development is unlikely to be ongoing. Therefore, DOE determined that this technology option would not be practicable to manufacture, install, and service on a scale necessary to serve the relevant market at the time of the projected compliance date of any new or amended consumer clothes dryer standards and did not consider it for further analysis.

e. Ultrasonic Drying, Electric Only

Researchers at ORNL have developed an ultrasonic drying prototype that uses piezoelectric transducers to separate water from clothes through water cavitation produced by ultrasonic vibrations. According to their research, the energy imparted to the water must overcome surface tension in order to break the water into droplets, but this energy is substantially less than the latent heat of vaporization of water, which is the primary thermodynamic barrier for conventional evaporation drying. The ORNL researchers anticipate that ultrasonic drying technology will result in an energy factor[41] of greater than 10 and a drying time of less than 20 minutes.[42] Because this technology is still in the prototype stage, however, DOE determined that this technology option would not be practicable to manufacture, install, and service on a scale necessary to serve the relevant market at the time of the projected compliance date of any new or amended consumer clothes dryer standards and did not consider it for further analysis.

DOE did not receive any comments in response to the August 2022 NOPR regarding these screened out technology options, and for the reasons discussed, screened out the same technologies for this direct final rule analysis.

2. Remaining Technologies

Through a review of each technology, DOE tentatively concludes that all of the other identified technologies listed in section IV.A.2 of this document met all screening criteria to be examined further as design options in DOE's direct final rule analysis. In summary, DOE did not screen out the following technology options:

TABLE IV.3—RETAINED DESIGN OPTIONS FOR CONSUMER CLOTHES DRYERS

Dryer Control or Drum Upgrades:
Improved termination
Modified operating conditions
Improved air circulation
Increased insulation
Improved drum design
Methods of Exhaust Heat Recovery (vented models only):
Recycle exhaust heat
Inlet air preheat
Inlet air preheat, condensing mode
Moisture Removal Options:
Heat pump, electric only
Modulating heat
Component Improvements:
Improved motor efficiency
Improved fan efficiency
Standby Power Improvements:
Transformerless Power Supply with Auto-Powerdown

[37] S. Ashley. 1998. ''Energy-Efficient Appliances,'' Mechanical Engineering Magazine, March 1998, pp. 94–97.

[38] E. Spagat. 2002. ''Whirlpool Goes Portable to Sell Dryers to Gen Y,'' Wall Street Journal, June 4, 2002.

[39] J.F. Gerling. 2003. ''Microwave Clothes Drying—Technical Solutions to Fundamental Challenges,'' Appliance Magazine, April 2003, p. 120.

[40] Cool Dry did not specify the metric or test method used to determine the efficiency of its prototype.

[41] This energy factor incorporates only active mode energy use and not standby mode and off mode energy use.

[42] Momen, A. *Ultrasonic Clothes Dryer: 2016 Building Technologies Office Peer Review.* 2016. Prepared for the U.S. Department of Energy at Oak Ridge National Laboratory, in partnership with the University of Florida and General Electric, p. 2.

DOE determined that these technology options are technologically feasible because they are being used or have previously been used in commercially available products or working prototypes. DOE also finds that all of the remaining technology options meet the other screening criteria (*i.e.,* practicable to manufacture, install, and service and do not result in adverse impacts on consumer utility, product availability, health, or safety). For additional details, *see* chapter 4 of the direct final rule TSD.

As previously discussed, on February 14, 2024, DOE received a second joint statement from the same group of stakeholders that submitted the Joint Agreement in which the signatories reaffirmed the standards recommended in the Joint Agreement.[43] In particular, the letter states that the joint stakeholders do not anticipate the recommended standards will negatively affect features or performance.

C. Engineering Analysis

The purpose of the engineering analysis is to establish the relationship between the efficiency and cost of consumer clothes dryers. There are two elements to consider in the engineering analysis: the selection of efficiency levels to analyze (*i.e.,* the efficiency analysis) and the determination of product cost at each efficiency level (*i.e.,* the cost analysis). In determining the performance of higher efficiency products, DOE considers technologies and design option combinations not eliminated by the screening analysis. For each product class, DOE estimates the baseline cost, as well as the incremental cost for the product/equipment at efficiency levels above the baseline. The output of the engineering analysis is a set of cost-efficiency ''curves'' that are used in downstream analyses (*i.e.,* the LCC and PBP analyses and the NIA).

1. Efficiency Analysis

DOE typically uses one of two approaches to develop energy efficiency levels for the engineering analysis: (1) relying on observed efficiency levels in the market (*i.e.,* the efficiency-level approach), or (2) determining the incremental efficiency improvements associated with incorporating specific design options to a baseline model (*i.e.,* the design-option approach). Using the efficiency-level approach, the efficiency levels established for the analysis are determined based on the market distribution of existing products (in other words, based on the range of efficiencies and efficiency-level ''clusters'' that already exist on the market). Using the design-option approach, the efficiency levels established for the analysis are determined through detailed engineering calculations and/or computer simulations of the efficiency improvements from implementing specific design options that have been identified in the technology assessment. DOE may also rely on a combination of these two approaches. For example, the efficiency-level approach (based on actual products on the market) may be extended using the design-option approach to interpolate to define ''gap fill'' levels (to bridge large gaps between other identified efficiency levels) and/or to extrapolate to the ''max-tech'' level (particularly in cases where the ''max-tech'' level exceeds the maximum efficiency level currently available on the market).

For this direct final rule, DOE used an efficiency-level approach, supplemented with reverse engineering. This approach involved first testing and then physically disassembling a representative sample of commercially available products, reviewing publicly available cost information, and modeling equipment cost. From this information and through the reverse engineering process, DOE estimated the manufacturer production costs (''MPCs'') for a range of products currently available on the market, considering the design options and the steps manufacturers would likely take to reach a certain efficiency level. As part of this analysis, DOE included test units that represent baseline models, newly introduced units on the market, units with unique configurations, and units with technologies as observed in the technology assessment. The efficiency levels analyzed as part of this engineering analysis are attainable using commercially available clothes dryer technologies, or technologies that have been demonstrated in working prototypes.

a. Baseline Efficiency Levels

For each product/equipment class, DOE generally selects a baseline model as a reference point for each class, and measures changes resulting from potential energy conservation standards against the baseline. The baseline model in each product/equipment class represents the characteristics of a product/equipment typical of that class (*e.g.,* capacity, physical size). Generally, a baseline model is one that just meets current energy conservation standards, or, if no standards are in place, the baseline is typically the most common or least efficient unit on the market.

The baseline clothes dryer efficiency levels for this direct final rule differ from the existing energy conservation standards that were established in the 2011 rulemaking analysis primarily due to the difference between the then-current appendix D1, which DOE used to evaluate products in the previous rulemaking, and the present version of appendix D2, established in the October 2021 TP Final Rule and which DOE used as the basis for this analysis. Appendix D2 includes test methods that more accurately measure the effects of automatic cycle termination and that may result in differences in the total measured energy consumption of the test cycle as compared to the test methods in appendix D1. Specifically, for automatic termination control dryers, appendix D2 requires a lower FMC of the test load and does not rely on a field use factor to account for the over-drying energy consumption, instead requiring that the automatic termination drying program run to the end of the cycle. Additionally, appendix D2 contains instructions for the testing of timer dryers, which include a lower FMC of the test load as compared to the version of appendix D1 used for the 2011 rulemaking analysis.

For the engineering analysis, DOE began by identifying the efficiency level corresponding to the Federal minimum energy conservation standards for each product class. Due to the test procedure changes adopted in the October 2021 Final Rule, DOE determined the baseline efficiency level representative of minimally compliant products when tested under appendix D2. To identify the appendix D2 baseline levels, DOE tested 22 models that were certified as minimally compliant with the current energy conservation standards, from across all product classes. Because certified performance data are not available for models on the market tested in accordance with both appendix D1 and appendix D2, DOE tested each basic model in its test sample in accordance with appendix D1 and appendix D2 and used the test values for appendix D2 to determine the baseline models in support of this engineering analysis. Due to the differences in the two test procedures previously described, the baseline CEF_{D2} measured using appendix D2 is numerically lower for each product class than the corresponding CEF_{D1} value in the current energy conservation standards, though that does not indicate a lower efficiency. The test procedure differences drive the lower baseline

[43] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058.*

CEF_{D2} values and do not represent a lower efficiency or backsliding.

With regard to the vented gas compact product class, DOE is unaware of any currently available commercial products that fall within the vented gas compact product class. To determine the baseline level for this product class, DOE analyzed a vented gas compact-size model that was previously available on the market prior to the effective date of the current energy conservation. DOE's previous testing of that model—which utilized electromechanical controls—suggests that the model would not be compliant with the existing standards. DOE expects that manufacturers would implement electronic controls as a design option to produce vented gas compact clothes dryers that minimally comply with the existing standard. DOE determined the efficiency performance that would be achieved through the addition of electronic controls by applying the same relative efficiency improvement observed with the implementation of electronic controls for standard-size vented gas clothes dryers, as shown in Table IV.8 in section IV.C.1.b of this document. The resulting estimated level of baseline performance for the vented gas compact product class is consistent with the efficiency level recommended by the Joint Agreement for this product class.

The baseline efficiency levels considered for this analysis are presented along with the current standards in Table IV.4 and are discussed in more detail in chapter 5 of the direct final rule TSD. The baseline values are the same as those proposed in the August 2022 NOPR, except for the vented gas compact product class as discussed.

TABLE IV.4—DIRECT FINAL RULE CONSUMER CLOTHES DRYER BASELINE EFFICIENCY LEVELS

Product class	CEF_{D1} (lb/kWh)	CEF_{D2} (lb/kWh) *
(i) Electric, Standard (4.4 ft^3 or greater capacity)	3.73	2.20
(ii) Electric, Compact (120V) (less than 4.4 ft^3 capacity)	3.61	2.36
(iii) Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	3.27	2.00
(iv) Vented Gas, Standard (4.4 cubic ft^3 or greater capacity)	3.30	2.00
(v) Vented Gas, Compact (less than 4.4 ft^3 capacity)	3.30	2.02
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	2.55	2.03
(vii) Ventless Electric, Combination Washer-Dryer	2.08	2.27

* As discussed, the baseline CEF_{D2} values represent differences in test procedure between appendix D1 and appendix D2 and do not constitute backsliding. CEF_{D2} baseline efficiency levels as measured under appendix D2 account for differences in the effectiveness of automatic cycle termination. Manufacturers implement automatic termination in a variety of ways, which will impact the representations as measured under appendix D2 and result in a range of possible CEF_{D2} values, as compared to the CEF_{D1} values in the existing Federal standards.

b. Incremental Efficiency Levels

DOE developed incremental efficiency levels by reviewing products currently available on the market and by testing and reverse engineering products in the DOE test sample in support of the direct final rule. For each product class, DOE analyzed several efficiency levels and determined the incremental MPC at each of these levels. DOE initially reviewed data in DOE's Compliance Certification Database (''CCD'') to evaluate the range of efficiencies for consumer clothes dryers currently available on the market. As discussed in chapter 5 of the direct final rule TSD, non-ENERGY STAR-qualified products (*i.e.,* generally units with lower-rated efficiencies) are typically tested using appendix D1, while ENERGY STAR-qualified products are required to be tested using appendix D2. As a result, DOE conducted testing on a representative sample of non-ENERGY STAR-qualified products using appendix D2 to determine appropriate initial incremental efficiency levels for each product class. DOE observed that while electronic controls are typically implemented with other design options in this analysis, the improved automatic termination precision offered by switching to electronic controls contributed significantly to an increase in efficiency. This efficiency gain informed the first incremental efficiency levels for most product classes and was noted simply as electronic controls in the design options listed in the tables later in this section. The design options associated with higher efficiency levels were subsequently distinguished according to specific design options DOE found manufacturers used to meet these higher efficiencies. As part of DOE's analysis, the maximum available efficiency level is the highest efficiency unit currently available on the market. DOE also defines a ''max-tech'' efficiency level to represent the maximum possible efficiency for a given product.

For the vented gas compact product class, no units were available on the market at the time of the analysis whose rated value exceeded the baseline level. Given recent market trends, DOE does not have reason to expect manufacturers to re-introduce compact-size vented gas clothes dryers to the market, regardless of amendments to energy conservation standards. Accordingly, DOE did not consider any higher efficiency levels for this product class.

In defining the incremental efficiency levels for the other product classes for this direct final rule, DOE considered comments it had received in response to the incremental efficiency levels proposed in the August 2022 NOPR, including several from commenters who support the Joint Agreement.

The CA IOUs supported DOE's decision to adopt the updated max-tech levels as indicative of the growth and maturity of heat pump technologies for vented and ventless products. The CA IOUs further commented that adopting the max-tech levels sets a key precedent for subsequent DOE energy efficiency and non-DOE rulemakings to represent the true potential of a product class. (California IOUs, No. 50 at pp. 4–5)

AHAM and Whirlpool disagreed with DOE's tentative determination that the proposed standards in the August 2022 NOPR would allow for electromechanical controls. AHAM and Whirlpool commented that electronic controls are required to enable the technology options for the proposed TSL. Whirlpool further commented that electromechanical control dryers are not sophisticated enough to enable the other technology options that DOE described in the August 2022 NOPR analysis and therefore could not be used effectively with the appendix D2 test procedure. Whirlpool stated that DOE's NOPR analysis missed several key aspects where utility and performance could be lessened in order to meet the proposed standard levels. Whirlpool noted that the average CEF score of the five tested units in the vented electric standard product class with electromechanical

controls in the August 2022 NOPR analysis is 2.64 lb/kWh, over 30-percent lower than the proposed standard. AHAM stated that electromechanical controls have consumer utility in that they are easy to use and reduce the overall costs associated with the product, and that requiring electronic controls would result in investment costs for manufacturers and increased purchase prices for consumers. AHAM requested that DOE retain electromechanical controls among a consumer's purchase options as, according to AHAM, they are a desirable feature for reliability, they provide reduced appliance cost among consumers, and their elimination from the market would likely cause consumers to postpone the purchase of new dryers, in turn increasing the total national energy consumption. Whirlpool stated concern regarding a forced regulatory phaseout of electromechanical controls because they are incorporated in a popular and affordable segment of consumer clothes dryers, and noted that although some electronic controls could be ''hidden'' from the consumer, there could be some lost utility from the easy and low-cost repairability of electromechanical control dryers. (AHAM, No. 46 at pp. 5, 10; Whirlpool, No. 53 at pp. 3–4)

DOE is not aware of reliability issues associated with the implementation of electronic controls relative to electromechanical controls. However, DOE acknowledges that a transition from electromechanical controls to electronic controls may require manufacturer investment costs to redesign products and would likely increase purchase price for consumers, as captured in the incremental costs estimated and presented in this direct final rule analysis. Based on its analysis for this direct final rule, DOE believes that component costs associated with the implementation of electronic controls are lower than those estimated in the August 2022 NOPR analysis, which is reflected in the updated MPCs for the efficiency levels that entail a shift to electronic controls. These costs are reflected in the MPCs, which are the basis for the LCC and PBP analyses, in which consumer impacts related to increased purchase price and repair and maintenance costs are considered. Additionally, DOE reevaluated repair costs and accordingly implemented higher repair costs associated with electronic controls in this direct final rule analysis, consistent with Whirlpool's comments. *See* section IV.F of this document and chapter 8 of the direct final rule TSD for additional details.

Regarding the concern that clothes dryers equipped with electromechanical controls could not be tested under appendix D2, DOE notes that its test sample shows that requiring the use of the appendix D2 test procedure will not preclude the use of electromechanical controls. As discussed in chapter 5 of the direct final rule TSD, DOE tested baseline models with electromechanical controls under appendix D2, where available. For the ventless electric compact (240V) product class and the ventless electric combination washer-dryer product class, there were no baseline models identified with electromechanical controls; however, the same efficiency-level approach was taken to establish the efficiency-level structures for these product classes. The baseline efficiency levels in this direct final rule represent a minimally compliant, basic-construction consumer clothes dryer on the market, such as a dryer with electromechanical controls, and were set according to the lowest tested values under appendix D2 in each product class. As Whirlpool noted, the average CEF score of the five tested units in the vented electric standard product class with electromechanical controls was significantly lower than the proposed standard, further indicating the efficiency savings associated with a transition to a combination of electronic controls and higher design options. Regarding the concern that the proposed amended standards would require the implementation of electronic controls, DOE reiterates that although it expects that electronic controls are most likely to be used to achieve higher efficiency levels, and a review of ENERGY STAR-qualified products suggests increased prevalent use of electronic controls, manufacturers are not required to implement these specific design options to meet amended standards. DOE therefore does not expect the amended standards to preclude electromechanical controls should manufacturers choose to implement them.

Regarding AHAM and Whirlpool's comments that the required implementation of electronic controls to reach efficiency levels above the existing standard may result in a loss of consumer utility associated with the traditional user interface utilizing electromechanical controls, DOE's testing and analysis of models currently on the market confirms Whirlpool's statement that electronic controls may be ''hidden'' from consumers who prefer a more traditional user interface. This may be accomplished by implementing physical dials for consumer use that in turn manipulate the electronic controls in order to achieve the efficiency savings associated with electronic controls while providing the user experience of electromechanical controls. Therefore, even if electronic controls are utilized, DOE does not expect a loss in consumer utility associated with the use of electromechanical controls. DOE notes that AHAM recommended the proposed efficiency levels in the Joint Agreement on behalf of its members, including Whirlpool, in the Joint Agreement, which includes efficiency levels that can be achieved with the implementation of electronic controls.

Whirlpool stated that there may be greater visibility and scrutiny of drying times associated with electronic control clothes dryers among consumers, as electromechanical control dryers do not display drying times. According to Whirlpool, consumers may believe they are losing control of their dryers in a way that results in additional energy consumption, and DOE should account for this possible behavioral shift and lost energy savings. (Whirlpool, No. 53 at p. 7)

DOE is not aware of any data suggesting that the behavior of consumers of with clothes dryers utilizing electronic controls results in greater energy use than for consumers with clothes dryers utilizing electromechanical controls and notes that electronic controls are typically more efficient than electromechanical controls. As previously noted, manufacturers currently provide electronic controls that provide the experience of electromechanical controls through the use of dials which would avoid any loss in consumer utility.

GEA stated that while the appendix D2 test procedure requires use of the ''normal'' or ''medium'' dryness setting for the clothes dryer test cycle, most labs, according to GEA, understand the ''optimum'' dryness setting to be the ''normal'' setting for appendix D2. GEA stated that it provides further clarity to consumers and test labs in the use and care manual for products with an ''optimum'' dryness setting by specifying that optimum is the dryness setting to use for most clothes when running the ''cottons'' cycle (the drying cycle recommended for certain consumer clothes dryers manufactured by GEA for drying cotton). Therefore, based on the cycle settings provided by the additional test information DOE published on October 13, 2022, and information provided by Guidehouse to GEA under a non-disclosure agreement,

GEA stated that DOE incorrectly tested two models in its test sample and urged DOE to either rerun its testing, exclude the models in question from its analysis, or accept the data provided by GEA and adjust its savings model. (GEA, No. 49 at pp. 2–3)

DOE notes that the baseline units GEA referenced are certified under appendix D1, and although these units were not originally intended to be tested under the appendix D2 test procedure, DOE tested them using the appropriate cycle settings under the appendix D2 test procedure to support the engineering analysis. These settings were different than the ''optimum'' dryness setting specified in the use and care manual for these particular units. Although GEA referred to specific cycle settings for consumer use, DOE notes that this instruction for cycle settings does not supersede the requirements of the appendix D2 test procedure. Additionally, DOE notes that the test cycle settings used were within the range anticipated and not expressly warned against by the owner's manual or use and care manual. Therefore, DOE maintains that the correct cycle settings were used to test the units in question.

Whirlpool stated that DOE should have presented the cycle times before and after wrinkle prevention mode was enabled for models in the test sample that had wrinkle prevention mode on by default. Whirlpool further stated that models reported in the data had extremely long cycle times, between 88 and 319 minutes, but that such times were distorted due to testing with wrinkle protection mode enabled. Additionally, Whirlpool stated that testing of consumer clothes dryers with wrinkle prevention mode enabled by default may have distorted some of the tested settings and the resulting CEF scores because wrinkle prevention results in additional cycle time of continuous tumbling after the heating element has been turned off. Whirlpool stated that, this results in an energy penalty as the additional cycle time potentially allows for moisture absorption in the test load to the point of failing to meet the required FMC of 2 percent, and therefore a retest is required using the highest dryness level setting associated with more energy consumption and thus a lower average measured CEF. Whirlpool further stated that wrinkle prevention mode does not produce an accurate comparison of average cycle times and CEF scores of these dryers compared to other dryers that do not have wrinkle prevention modes enabled by default, and DOE should have also recorded the CEF scores, FMC, and drying times of these models before they were allowed to enter wrinkle prevention mode. Whirlpool stated that this data should have been used to inform comparisons between dryers and the development of baseline efficiency levels. Whirlpool stated that if these dryers were designed to the appendix D2 test procedure, wrinkle prevention mode would likely not have been enabled by default. (Whirlpool, No. 53 at pp. 9–10)

In the August 2013 TP Final Rule, DOE clarified that if a clothes dryer is equipped with a wrinkle prevention mode that is activated by default in the as-shipped position, the cycle shall be considered complete after the end of the wrinkle prevention mode. 76 FR 49607, 49623–49624. Although wrinkle prevention mode may have been disabled had the test units been designed for appendix D2 testing, DOE stated previously that accurate testing of existing baseline units according to the appendix D2 test procedure was essential for the analysis, including the use of optional cycle settings that are enabled by default and that do not affect the program, temperature, or dryness settings. The test procedure in appendix D2 therefore requires that testing include wrinkle prevention mode if it is enabled by default. DOE maintains, as it was unable to predict or assume the cycle settings Whirlpool would have selected had the test units been designed for appendix D2 testing, that the test units in question were properly tested in accordance with appendix D2 using the correct cycle settings consistent with the DOE test procedure.

Chapter 5 of the direct final rule TSD discusses the incremental efficiency levels for each of the product classes in this analysis. The revised CEF_{D2} efficiency levels for each product class are shown below in Table IV.5 through Table IV.10, along with the current energy conservation standards in CEF_{D1} for comparison. As discussed in section IV.C.1.a of this document, the baseline CEF_{D2} values estimated for the preliminary analysis are lower than the current CEF_{D1} values in the energy conservation standards due to the differences in testing between appendix D1 and appendix D2.

TABLE IV.5—DIRECT FINAL RULE ANALYSIS: ELECTRIC STANDARD EFFICIENCY LEVELS

Efficiency level (''EL'')	Design option	Current standard CEF_{D1} (lb/kWh)	DFR CEF_{D2} (lb/kWh) *
Baseline	Baseline (Electromechanical Controls)	3.73	2.20
1	Baseline + Electronic Controls		2.68
2	EL1 + Optimized Heating System		3.04
3	EL2 + More Advanced Automatic Termination Control System		3.27
4	EL3 + Modulating (2-Stage) Heat		3.93
5	EL4 + Inlet Air Preheat		4.21
6	Hybrid Heat Pump Dryer (Additional Resistance Heater)		5.20
7	Heat Pump Dryer (Max-Tech)		[44] 7.39

* As discussed above, the baseline CEF_{D2} values represent differences in test procedure between appendix D1 and appendix D2 and do not constitute backsliding.

[44] DOE is aware of consumer clothes dryers in the electric standard product class that perform at higher efficiencies than the proposed max-tech level, but those models are not representative of the typical capacity in the electric standard product class. Therefore, based on the certified performance of those models and additional investigative testing, DOE determined a representative max-tech efficiency for the electric standard product class that reflects an appropriate, representative unit capacity. *See* chapter 5 of the final rule TSD for more information.

TABLE IV.6—DIRECT FINAL RULE ANALYSIS: ELECTRIC COMPACT (120V)—EFFICIENCY LEVELS

Efficiency level	Design option	Current standard CEF_{D1} (lb/kWh)	DFR CEF_{D2} (lb/kWh)
Baseline	Baseline (Electromechanical Controls)	3.61	2.36
1	Baseline + Electronic Controls		3.15
2	EL1 + Optimized Heating System		3.35
3	EL2 + More Advanced Automatic Termination Control System		4.28
4	EL3 + Modulating (2-Stage) Heat		4.33
5	EL4 + Inlet Air Preheat		4.63
6	Heat Pump Dryer (Max-Tech)		6.37

TABLE IV.7—DIRECT FINAL RULE ANALYSIS: VENTED ELECTRIC COMPACT (240V) EFFICIENCY LEVELS

Efficiency level	Design option	Current standard CEF_{D1} (lb/kWh)	DFR CEF_{D2} (lb/kWh)
Baseline	Baseline (Electromechanical Controls)	3.27	2.00
1	Baseline + Electronic Controls		2.44
2	EL1 + Optimized Heating System		2.76
3	EL2 + More Advanced Automatic Termination Control System		3.30
4	EL3 + Modulating (2-Stage) Heat		3.57
5	EL4 + Inlet Air Preheat		3.82
6	Heat Pump Dryer (Max-Tech)		3.91

TABLE IV.8—DIRECT FINAL RULE ANALYSIS: VENTED GAS STANDARD EFFICIENCY LEVELS

Efficiency level	Design option	Current standard CEF_{D1} (lb/kWh) [45]	DFR CEF_{D2} (lb/kWh)
Baseline	Baseline (Electromechanical Controls)	3.30	2.00
1	Baseline + Electronic Controls		2.44
2	EL1 + Optimized Heating System and More Advanced Automatic Termination Control System.		3.00
3	EL2 + Modulating (2-Stage) Heat		3.48
4	EL3 + Inlet Air Preheat (Max-Tech)		3.83

TABLE IV.9—DIRECT FINAL RULE ANALYSIS: VENTLESS ELECTRIC COMPACT (240V) EFFICIENCY LEVELS

Efficiency level	Design option	Current standard CEF_{D1} (lb/kWh)	DFR CEF_{D2} (lb/kWh)
Baseline	Baseline (Electronic Controls)	2.55	2.03
1	Baseline + More Advanced Automatic Termination Control System		2.68
2	Heat Pump Dryer (Max-Tech)		6.80

TABLE IV.10—DIRECT FINAL RULE ANALYSIS: VENTLESS ELECTRIC COMBINATION WASHER-DRYER EFFICIENCY LEVELS

Efficiency level	Design option	Current standard CEF_{D1} (lb/kWh)	DFR CEF_{D2} (lb/kWh)
Baseline	Baseline (Electronic Controls)	2.08	2.27
1	Baseline + High-Speed Spin		2.33
2	Heat Pump Dryer (Max-Tech)		4.01

[45] The current standard does not distinguish a separate product class for compact-size gas consumer clothes dryers. As such, the current standard may apply to all gas consumer clothes dryers.

2. Cost Analysis

The cost analysis portion of the engineering analysis is conducted using one or a combination of cost approaches. The selection of cost approach depends on a suite of factors, including the availability and reliability of public information, characteristics of the regulated product, and the availability and timeliness of purchasing the product on the market. The cost approaches are summarized as follows:

- *Physical teardowns:* Under this approach, DOE physically dismantles a commercially available product, component by component, to develop a detailed bill of materials for the product.
- *Catalog teardowns:* In lieu of physically deconstructing a product, DOE identifies each component using parts diagrams (available from manufacturer websites or appliance repair websites, for example) to develop the bill of materials for the product.
- *Price surveys:* If neither a physical nor catalog teardown is feasible (for example, for tightly integrated products such as fluorescent lamps, which are infeasible to disassemble and for which parts diagrams are unavailable) or cost-prohibitive and otherwise impractical (*e.g.,* large commercial boilers), DOE conducts price surveys using publicly available pricing data published on major online retailer websites and/or by soliciting prices from distributors and other commercial channels.

In the present case, DOE conducted the analysis using physical product teardowns to determine the baseline MPC for each product class as outlined in chapter 5 of the direct final rule TSD. DOE developed the cost-efficiency relationships for each product class as discussed in section IV.C.3 of this document. DOE developed incremental MPCs based on product teardowns and manufacturing cost modeling of the expected design changes at each efficiency level. DOE observed that the basic product designs of vented electric and vented gas clothes dryers are similar except for the heating system. DOE also observed that the technology designs of standard-size and compact-size consumer clothes dryers are similar as well, simply scaled in size. As a result, in the absence of models available on the market at certain efficiency levels for certain product classes, DOE estimated the incremental MPC for these based on the same design changes observed for the electric standard product class. DOE updated the cost-efficiency analysis from the preliminary analysis by updating the costs of raw materials and purchased components, as well as updating costs for manufacturing equipment, labor, and depreciation. DOE also used information from the teardown of units in the updated test sample to inform updates to the cost-efficiency analysis. Not all units in the updated test sample were torn down; DOE focused on units recently introduced in the market, units with unique configuration, and units with technologies that were not available at the time of the preliminary analysis to better inform the costs associated with particular product classes and design options.

The resulting bill of materials provides the basis for the MPC estimates in this direct final rule. The baseline MPCs for each consumer clothes dryer product class are listed in Table IV.11, with all costs presented in 2022 dollars.

TABLE IV.11—DIRECT FINAL RULE ANALYSIS: CONSUMER CLOTHES DRYER BASELINE MANUFACTURER PRODUCTION COSTS

Product class	Baseline MPC (2022$)
(i) Electric, Standard (4.4 cubic feet (ft^3) or greater capacity)	268.90
(ii) Electric, Compact (120 volts (V)) (less than 4.4 ft^3 capacity)	284.06
(iii) Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	284.91
(iv) Vented Gas, Standard (4.4 cubic ft^3 or greater capacity)	303.39
(v) Vented Gas, Compact (less than 4.4 ft^3 capacity)	329.94
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	453.09
(vii) Ventless Electric, Combination Washer-Dryer	611.19

To account for manufacturers' non-production costs and profit margin, DOE applies a multiplier (the manufacturer markup) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. DOE developed an average manufacturer markup by examining the annual Securities and Exchange Commission (''SEC'') 10–K reports filed by publicly traded manufacturers primarily engaged in appliance manufacturing and whose combined product range includes consumer clothes dryers.[46] *See* section IV.J.2.d of this document and chapter 12 of the direct final rule TSD for additional information on the manufacturer markup.

3. Cost-Efficiency Results

The results of the engineering analysis are presented as cost-efficiency data for each of the efficiency levels for each of the product classes that were analyzed, as well as those extrapolated from a product class with similar features. DOE developed estimates of MPCs for each unit in the teardown sample to develop a comprehensive set of incremental MPCs (*i.e.,* the additional costs manufacturers would likely incur by producing consumer clothes dryers at each efficiency level compared to the baseline).

The resulting incremental MPCs from this analysis are provided in Table IV.12 through Table IV.17. *See* chapter 5 of the direct final rule TSD for additional detail on the engineering analysis.

[46] U.S. Securities and Exchange Commission, Electronic Data Gathering, Analysis, and Retrieval (''EDGAR'') system. Available at *www.sec.gov/edgar/search/* (last accessed April 21, 2023).

TABLE IV.12—DIRECT FINAL RULE ANALYSIS: ELECTRIC STANDARD INCREMENTAL MANUFACTURER PRODUCTION COSTS

Efficiency level	Design option	Incremental MPC (2022$)
Baseline	Baseline (Electromechanical Controls)	
1	Baseline + Electronic Controls	5.60
2	EL1 + Optimized Heating System	8.60
3	EL2 + More Advanced Automatic Termination Control System	9.15
4	EL3 + Modulating (2-Stage) Heat	15.19
5	EL4 + Inlet Air Preheat	60.11
6	Hybrid Heat Pump Dryer (Additional Resistive Heater)	231.01
7	Heat Pump Dryer (Max-Tech)	240.85

TABLE IV.13—DIRECT FINAL RULE ANALYSIS: ELECTRIC COMPACT (120V) INCREMENTAL MANUFACTURER PRODUCTION COSTS

Efficiency level	Design option	Incremental MPC (2022$)
Baseline	Baseline (Electromechanical Controls)	
1	Baseline + Electronic Controls	7.00
2	EL1 + Optimized Heating System	11.81
3	EL2 + More Advanced Automatic Termination Control System	12.63
4	EL3 + Modulating (2-Stage) Heat	19.43
5	EL4 + Inlet Air Preheat	70.28
6	Heat Pump Dryer (Max-Tech)	225.41

TABLE IV.14—DIRECT FINAL RULE ANALYSIS: VENTED ELECTRIC COMPACT (240V) INCREMENTAL MANUFACTURER PRODUCTION COSTS

Efficiency level	Design option	Incremental MPC (2022$)
Baseline	Baseline (Electromechanical Controls)	
1	Baseline + Electronic Controls	7.63
2	EL1 + Optimized Heating System	12.43
3	EL2 + More Advanced Automatic Termination Control System	13.26
4	EL3 + Modulating (2-Stage) Heat	20.06
5	EL4 + Inlet Air Preheat	70.90
6	Heat Pump Dryer (Max-Tech)	226.03

TABLE IV.15—DIRECT FINAL RULE ANALYSIS: VENTED GAS STANDARD INCREMENTAL MANUFACTURER PRODUCTION COSTS

Efficiency level	Design option	Incremental MPC (2022$)
Baseline	Baseline (Electromechanical Controls)	
1	Baseline + Electronic Controls	9.64
2	EL1 + Optimized Heating System and More Advanced Automatic Termination Control System	11.55
3	EL2 + Modulating (2-Stage) Heat	21.59
4	EL3 + Inlet Air Preheat (Max-Tech)	66.52

TABLE IV.16—DIRECT FINAL RULE ANALYSIS: VENTLESS ELECTRIC COMPACT (240V) INCREMENTAL MANUFACTURER PRODUCTION COSTS

Efficiency level	Design option	Incremental MPC (2022$)
Baseline	Baseline (Electronic Controls)	
1	Baseline + More Advanced Automatic Termination Control System	2.35
2	Heat Pump Dryer (Max-Tech)	196.51

TABLE IV.17—DIRECT FINAL RULE ANALYSIS: VENTLESS ELECTRIC COMBINATION WASHER-DRYER INCREMENTAL MANUFACTURER PRODUCTION COSTS

Efficiency level	Design option	Incremental MPC (2022$)
Baseline	Baseline (Electronic Controls)	
1	Baseline + High-Speed Spin	*0.00
2	Heat Pump Dryer (Max-Tech)	420.04

*Most ventless electric combination washer-dryers are already equipped with a spin-only mode option as a standard feature resulting in an incremental MPC of $0.00 for this design option.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.,* manufacturer markups, retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert the MSP estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis. At each step in the distribution channel, companies mark up the price of the product to cover business costs and profit margin.

DOE considered two distribution channels through which consumer clothes dryers move from manufacturers to consumers. The majority of consumer clothes dryer sales go through the direct retailer channel, in which manufacturers sell the products directly to retailers, who then sell to consumers. This direct retailer channel accounts for 90 percent of the consumer clothes dryer market. The rest of the market goes through a separate new construction distribution channel, in which manufacturers sell the products to wholesalers, who in turn sell the products to general contractors, then to consumers. The main parties in the post-manufacturer distribution channels are retailers, wholesalers, and contractors.

DOE developed baseline and incremental markups for each actor in the distribution channels. Baseline markups are applied to the price of products with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.[47]

DOE relied on economic data from the U.S. Census Bureau to estimate average baseline and incremental markups. Specifically, DOE used the 2017 Annual Retail Trade Survey for the ''electronics and appliance stores'' sector to develop retailer markups;[48] the 2017 Annual Wholesale Trade Survey for ''household appliances, and electrical and electronic goods merchant wholesalers'' to estimate wholesaler markups;[49] and the 2017 Economic Census for the residential construction sector to derive general contractor markups.[50]

Chapter 6 of the direct final rule TSD provides details on DOE's development of markups for consumer clothes dryers.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of consumer clothes dryers at different efficiencies in representative U.S. single-family homes, multifamily residences, and mobile homes and to assess the energy savings potential of increased consumer clothes dryer efficiency. The energy use analysis estimates the range of energy use of consumer clothes dryers in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

In conducting the energy use analysis for this direct final rule, DOE considered comments it had received in response to the proposed analysis in the August 2022 NOPR. DOE received a comment from AHAM regarding the number of annual use cycles in the August 2022 NOPR energy use analysis. AHAM requested that DOE review the 2020 Residential Energy Consumption Survey (''2020 RECS'') data[51] and adjust the annual number of cycles accordingly. AHAM stated that it previously commented that RECS 2015 suggested an annual number of cycles of 236 as opposed to the 283 cycles in the current test procedure, which is consistent with the observation that clothes washer cycles have decreased in number to 234 cycles per year using the 2015 RECS. According to AHAM, it does not make sense for clothes washer cycles to decrease and clothes dryer cycles to increase or even stay the same. AHAM suggested that based on the 2020 RECS, the annual number of cycles should be 209. (AHAM, No. 46 at p. 12)

In the August 2022 NOPR analysis, DOE used data from the EIA's 2015 Residential Energy Consumption Survey (''2015 RECS'') to establish a reasonable range of energy consumption in the field for consumer clothes dryers. DOE noted that the microdata for the 2020 RECS was not available at the time the NOPR analysis was conducted but stated that it would update the underlying data to 2020 RECS if it was available prior to the final rule. 87 FR 51762. DOE is aware that the 2020 RECS has been published.[52] This survey collected data from 18,496 housing units and was designed by EIA to represent the household population in the United States. Therefore, DOE has integrated this data into its analysis for the direct final rule concerning households using clothes dryers.

DOE divided the sample of households into four subsamples for the product classes being analyzed:

[47] Because the projected price of standards-compliant products is typically higher than the price of baseline products, using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible, DOE maintains that in markets that are reasonably competitive it is unlikely that standards would lead to a sustainable increase in profitability in the long run.

[48] U.S. Census Bureau, *Annual Retail Trade Survey.* 2017. Available at *www.census.gov/programs-surveys/arts.html* (last accessed Feb. 1, 2022).

[49] U.S. Census Bureau, Annual Wholesale Trade Survey. 2017. Available at *www.census.gov/wholesale/index.html* (last accessed Feb. 1, 2022).

[50] U.S. Census Bureau. 2017 Economic Census: Construction Industry Series: Detailed Statistics for Establishments: 2017. New Single-Family General Contractors, New Multifamily Housing Construction (Except Operative Builders), New Housing Operative Builders, and Residential Remodelers. Sector 23: 236115 through 236118. 2017. U.S. Census.

[51] The Residential Energy Consumption Survey 2020 data is available at *www.eia.gov/consumption/residential/data/2020/.*

[52] U.S. Department of Energy—Energy Information Administration, *Residential Energy Consumption Survey: 2020 Public Use Data Files.* Available at *www.eia.gov/consumption/residential/data/2020/index.php?view=microdata* (last accessed April 21, 2023).

standard or compact consumer clothes dryers using electricity or natural gas as the dryer fuel. For compact consumer clothes dryers, DOE developed a subsample consisting of households with an electric or gas clothes dryer in multifamily buildings, manufactured homes, and single-family homes with less than 1,000 square feet and no garage or basement, since these products are most likely to be found in these housing types.

The energy use analysis requires DOE to establish a range of total annual usage (number of cycles) in order to estimate annual energy consumption by a clothes dryer. DOE estimated the number of clothes dryer cycles per year for each sample household using data from the 2020 RECS on the number of laundry loads washed (clothes washer cycles) per week and the frequency of clothes dryer use. The average annual energy consumption was then calculated, reflecting an average annual sample-weighted usage of 213 cycles per year.

For each considered efficiency level, DOE derived the field energy use by separately estimating the active mode and standby mode energy use and then adding them together. The per-cycle active mode energy consumption was estimated using the DOE clothes dryer test procedure at appendix D2. It was then back calculated from the test procedure results by dividing the weight (lb) of clothes dried per-cycle (*i.e.,* 8.45 lb for standard and 3 lb for compact consumer clothes dryers) by the CEF_{D2} (lb/kWh) and subtracting standby power. DOE adjusted the test procedure energy use to reflect field conditions by making an adjustment for clothes dryer load weight and moisture removal factor. Chapter 7 of the direct final rule TSD provides more detail about these calculations.

DOE also considered the impact of clothes dryer operation on home heating and cooling loads, given that a clothes dryer releases heat to the surrounding environment. If the clothes dryer is located indoors, its use will tend to slightly reduce the heating load during the heating season and slightly increase the cooling load during the cooling season. To calculate this impact, DOE first estimated whether the clothes dryer in a RECS sample home is located in conditioned space (referred to as ''indoors'') or in unconditioned space (*e.g.,* garages, unconditioned basements, outdoor utility closets, or attics). Based on the 2020 RECS and the 2019 American Housing Survey (''AHS''),[53] DOE assumed that 50 percent of vented standard electric and gas consumer clothes dryers are located indoors, while 100 percent of compact and ventless consumer clothes dryers are located indoors. For these installations, DOE used the results from a European Union study about the impacts of consumer clothes dryers on home heating and cooling loads to determine the appropriate factor to apply to the total clothes dryer energy use.[54] This study reported that for vented consumer clothes dryers, there is a factor of negative 3 to 9 percent (average 3 percent), and for ventless consumer clothes dryers there is a factor of positive 7 to 15 percent (average 11 percent).[55] This effect is likely to be approximately the same for all of the considered efficiency levels because the amount of air passing through the clothes dryer does not vary.

Chapter 7 of the direct final rule TSD provides details on DOE's energy use analysis for consumer clothes dryers.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards for consumer clothes dryers. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

- The LCC is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.
- The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-new-standards case, which reflects the estimated efficiency distribution of consumer clothes dryers in the absence of new or amended energy conservation standards. In contrast, the PBP for a given efficiency level is measured relative to the baseline product.

For each considered efficiency level in each product class, DOE calculated the LCC and PBP for a nationally representative set of housing units. As stated previously, DOE developed household samples from the 2020 RECS. For each sample household, DOE determined the energy consumption for the consumer clothes dryers and the appropriate energy price. By developing a representative sample of households, the analysis captured the variability in energy consumption and energy prices associated with the use of consumer clothes dryers.

Inputs to the calculation of total installed cost include the cost of the product—which includes MPCs, manufacturer markups, retailer and distributor markups, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, product lifetimes, and discount rates. DOE created distributions of values for product lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and consumer clothes dryer user samples. For this rulemaking, the Monte Carlo approach is implemented in MS Excel together with the Crystal Ball™ add-on.[56] The model calculated the LCC for products

[53] U.S. Census Bureau: Housing and Household Economic Statistics Division, American Housing Survey National Data. 2019, HUD. Available at *www.census.gov/programs-surveys/ahs/data/2019/ahs-2019-public-use-file--puf-.html* (last accessed April 6, 2023).

[54] Rüdenauer, I. and C.-O. Gensch, *Energy demand of tumble driers with respect to differences in technology and ambient conditions,* January 13, 2004. European Committee of Domestic Equipment Manufacturers (CECED).

[55] For units that are located in conditioned space, a negative factor for vented consumer clothes dryers translates to a penalty in energy use, whereas a positive factor for ventless consumer clothes dryers translates to a credit in energy use. For details of the calculations, *see* the Rüdenauer and Gensch study referenced above.

[56] Crystal Ball™ is a commercially available software tool to facilitate the creation of these types of models by generating probability distributions and summarizing results within Excel, available at *www.oracle.com/technetwork/middleware/crystalball/overview/index.html* (last accessed May 17, 2023).

at each efficiency level for 10,000 housing units per simulation run. The analytical results include a distribution of 10,000 data points showing the range of LCC savings for a given efficiency level relative to the no-new-standards case efficiency distribution. In performing an iteration of the Monte Carlo simulation for a given consumer, product efficiency is chosen based on its probability. If the chosen product efficiency is greater than or equal to the efficiency of the standard level under consideration, the LCC calculation reveals that a consumer is not impacted by the standard level. By accounting for consumers who already purchase more efficient products, DOE avoids overstating the potential benefits from increasing product efficiency. DOE calculated the LCC and PBP for consumers of consumer clothes dryers as if each were to purchase a new product in the first year of required compliance with new or amended standards. New and amended standards apply to consumer clothes dryers manufactured 3 years after the date on which any new or amended standard is published. (42 U.S.C. 6295(m)(4)(A)(i)) Therefore, DOE used 2027 as the first year of compliance with any amended standards for consumer clothes dryers for all the TSLs other than TSL 3. For TSL 3, DOE used 2028 as the first year of compliance for all product classes as specified for the Recommended TSL in the Joint Agreement.

Table IV.18 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 of the direct final rule TSD and its appendices.

TABLE IV.18—SUMMARY OF INPUTS AND METHODS FOR THE LCC AND PBP ANALYSIS *

Inputs	Source/method
Product Costs	Derived by multiplying MPCs by manufacturer and retailer markups and sales tax or by manufacturer, wholesaler, and general contractor markups and sales tax, as appropriate. Used historical data to derive a price scaling index to project product costs.
Installation Costs	Baseline installation cost determined with data from RSMeans Residential Cost Data 2022. Assumed no change with efficiency level.
Annual Energy Use	Total per-cycle energy use multiplied by the cycles per year. Average number of cycles based on field data. Variability: Based on the 2020 RECS (dryer usage), market data on remaining moisture content (RMC), and load weights.
Energy Prices	Electricity: Based on EIA's Form 861 data for 2022. Variability: Regional energy prices by Census Division.
Energy Price Trends	Based on *AEO2023* energy price projections.
Repair and Maintenance Costs	Repair costs vary between electromechanical and electronic control timers.
Product Lifetime	Average: 14 years.
Discount Rates	Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances or that might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances.
Compliance Date	TSL 1, TSL 2, TSL 4, TSL 5, and TSL 6: 2027. TSL 3 (The Recommended TSL): 2028.

* Not used for PBP calculation. References for the data sources mentioned in this table are provided in the following sections or in chapter 8 of the direct final rule TSD.

For this direct final rule, DOE considered comments it had received regarding the methodology for evaluating consumer economic impact that were submitted in response to the August 2022 NOPR. The approach used for this direct final rule is largely the same approach DOE had used for the August 2022 NOPR analysis.

In response to the August 2022 NOPR AHAM recommended that DOE modify the way consumer economic impact is analyzed and look at the probability that individual consumers will benefit from standards rather than whether the aggregate benefit is positive. (AHAM, No. 46 at p. 13)

In the LCC analysis, DOE notes that it does estimate the impact of potential standards on individual consumers in the household sample and considers the share of consumers that would benefit from a standard as part of its evaluation regarding whether particular standards are economically justified.

1. Product Cost

To calculate consumer product costs, DOE multiplied the MPCs developed in the engineering analysis by the markups described previously (along with sales taxes). DOE used different markups for baseline products and higher efficiency products because DOE applies an incremental markup to the increase in MSP associated with higher efficiency products.

Economic literature and historical data suggest that the real costs of many products may trend downward over time according to ''learning'' or ''experience'' curves. Experience curve analysis implicitly includes factors such as efficiencies in labor, capital investment, automation, materials prices, distribution, and economies of scale at an industry-wide level. To derive the learning rate parameter for consumer clothes dryers, DOE obtained historical Producer Price Index (''PPI'') data from the Bureau of Labor Statistics (''BLS'') for ''household laundry equipment'' between 1947 and 2016 and ''major household appliance: primary products'' between 2016 and 2022 to form a time series price index representing household laundry equipment from 1947 to 2022.[57] Inflation-adjusted price indices were calculated by dividing the PPI series by the gross domestic product index from the Bureau of Economic Analysis for the same years. Using this data from 1947 to 2022, the estimated learning rate (defined as the fractional reduction in price from each doubling of cumulative production) is 17.2 percent.

For this direct final rule, DOE considered comments it had received regarding the methodology for calculating consumer product costs that were submitted in response to the August 2022 NOPR. The approach used

[57] ''Household laundry equipment'' PPI (PCU3352203352204) is available through May 2016, and ''major household appliance: primary products'' PPI (PCU335220335220P) is available from May 2016 to present. *See* more information at *www.bls.gov/ppi/* (last accessed Nov. 29, 2021).

for this direct final rule is largely the same approach DOE had used for the August 2022 NOPR analysis.

In response to the August 2022 NOPR, AHAM stated that DOE's pricing estimates are incorrect because currently, publicly available retail market prices for the lowest-priced units (many of which are equipped with electromechanical controls) are approximately $400, and DOE's estimate for a baseline standard electric unit is $607. (AHAM, No. 46 at pp. 5–6, 8)

Whirlpool stated that DOE does not consider retail prices for models actually being sold in the market today that meet varying efficiency levels and actually utilize technology options needed to meet TSL 3. Whirlpool commented that retail price differences between $200 and $300 may be a better reflection of the expected price premiums for consumers from amended standards than DOE's analysis and methodology. (Whirlpool, No. 53 at p. 7)

In response, DOE notes that the actual retail price differences between a baseline and higher efficiency level currently on the market may include the price for other premium features in addition to engineering designs relating to efficiency. Additionally, retail prices reflect economies of scale in production as well as marketing strategies and profit margins of manufacturers and retailers. DOE maintains that its traditional approach, which has been subject to peer review, is better able to identify the incremental costs that are only connected to higher efficiency. Furthermore, in this direct final rule analysis, DOE leveraged web scraping to gather data on clothes dryer models available on the market from January to March 2023. The data was collected from major retail outlets, including Best Buy, Lowe's, and AJ Madison. DOE found that the lowest-priced baseline model cost $630. DOE therefore concluded that its baseline estimate for a standard electric unit is reasonable for this direct final rule.

2. Installation Cost

Installation cost includes labor, overhead, and any miscellaneous materials and parts needed to install the product. DOE used data from RSMeans Residential Cost Data to estimate the baseline installation cost for consumer clothes dryers.[58] DOE estimated that for the new construction market, it takes, on average, 1 hour to install a clothes dryer, while for the replacement or new-owner market, it takes 2.5 hours (*i.e.,* 1 hour for the trip charge, 30 minutes to remove the old clothes dryer, and 1 hour to install). DOE found no evidence that increased efficiency levels would impact installation costs.

3. Annual Energy Consumption

For each sampled household, DOE determined the energy consumption for a consumer clothes dryer at different efficiency levels using the approach described previously in section IV.E of this document.

4. Energy Prices

Because marginal electricity and gas prices more accurately capture the incremental savings associated with a change in energy use from higher efficiency, they provide a better representation of incremental change in consumer costs than average electricity and gas prices. Therefore, DOE applied average electricity and gas prices for the energy use of the product purchased in the no-new-standards case, and marginal electricity and gas prices for the incremental change in energy use associated with the other efficiency levels considered.

DOE derived electricity prices in 2022 using data from EEI Typical Bills and Average Rates reports. Based upon comprehensive, industry-wide surveys, this semi-annual report presents typical monthly electric bills and average kilowatt-hour costs to the customer as charged by investor-owned utilities. For the residential sector, DOE calculated electricity prices using the methodology described in Coughlin and Beraki (2018).[59]

DOE obtained data for calculating regional prices of natural gas from the EIA publication *Natural Gas*.[60] This publication presents monthly volumes of natural gas deliveries and average prices by state for residential, commercial, and industrial customers.

DOE's methodology allows electricity and gas prices to vary by sector, region, and season. In the analysis, variability in electricity and gas prices is chosen to be consistent with the way the consumer economic and energy use characteristics are defined in the LCC analysis. For consumer clothes dryers, DOE calculated weighted average values for average and marginal electricity and gas price for the nine census divisions. *See* chapter 8 of the direct final rule TSD for details.

To estimate energy prices in future years, DOE multiplied the 2022 energy prices by the projection of annual average price changes for each of the nine census divisions from the Reference case in *AEO2023,* which has an end year of 2050.[61] To estimate price trends after 2050, the 2046–2050 average was used for all years.

5. Maintenance and Repair Costs

Repair costs are associated with repairing or replacing product components that have failed in an appliance; maintenance costs are associated with maintaining the operation of the product. Past rules indicate in general that small, incremental increases in product efficiency produce no, or only minor, changes in repair and maintenance costs compared to baseline efficiency products. 76 FR 22454.

For consumer clothes dryers, DOE derived an annualized repair rate based on Consumer Reports data on repair and maintenance issues for consumer clothes dryers. DOE estimated that the average repair rate (which measures the repair frequency) for electric and gas consumer clothes dryers is 12 percent and 14 percent, respectively. The most likely repairs concern the electromechanical control unit or the electronic control unit. The repair costs are annualized by dividing by the average equipment lifetime of 14 years.

For this direct final rule, DOE considered comments it had received regarding the maintenance and repair costs that were submitted in response to the August 2022 NOPR. Whirlpool stated that DOE's NOPR analysis failed to adequately account for the increased repair costs associated with more advanced and expensive electronic parts in electronic control dryers, which would be mandated through DOE's proposed standards. Whirlpool commented that a timer replacement on an electromechanical control dryer will be significantly cheaper than the replacement of an equivalent failed component on an electronic control dryer, with major component differences being the timer, push-to-start button, rotary switch, buzzer, appliance control unit, and user interface assembly. (Whirlpool, No. 53 at pp. 8–9)

[58] RSMeans Online Residential Data (2022 Release). Gordian: Greenville, SC. Available at *www.rsmeansonline.com* (last accessed April 6, 2023).

[59] Coughlin, K. and B. Beraki. 2018. Residential Electricity Prices: A Review of Data Sources and Estimation Methods. Lawrence Berkeley National Laboratory. Berkeley, CA. Report No. LBNL–2001169. Available at *ees.lbl.gov/publications/residential-electricity-prices-review* (last accessed April 6, 2023).

[60] U.S. Department of Energy—Energy Information Administration. *Natural Gas Navigator* 2022. Available at *www.eia.gov/naturalgas/data.php* (last accessed April 6, 2023).

[61] U.S. Department of Energy—Energy Information Administration. *Annual Energy Outlook 2023 with Projections to 2050.* Washington, DC. Available at *www.eia.gov/forecasts/aeo/* (last accessed May 7, 2023).

As previously stated, for this direct final rule, DOE has updated its methodology for estimating repair costs and included repair costs associated with timer replacement in both electromechanical control and electronic control dryers. Based on the information provided by Whirlpool and a literature review, DOE estimated the repair cost to be $75 for an electromechanical control unit and $225 for an electronic control unit.

6. Product Lifetime

For consumer clothes dryers, DOE developed a distribution of lifetimes from which specific values were assigned to the appliances in the test sample. DOE analyzed actual lifetime in the field using a combination of historical shipments data, the stock of the considered appliances in the *American Housing Survey,* and responses in a number of RECS on the age of the appliances in the homes. The data allowed DOE to estimate a survival function, which provided an average appliance lifetime of approximately 14 years. From the 2015 RECS to the 2020 RECS, there was a 6-percent increase in the number of consumer clothes dryers retiring before reaching 4 years of age, and an additional 1 percent lasting beyond 15 years. Therefore, for this direct final rule, DOE's estimated average lifetime for consumer clothes dryers remains 14 years, with a distribution that includes 1 percent more dryers retiring before reaching 4 years and 2 percent more dryers remaining after 15 years and up to 30 years, compared to the NOPR Weibull lifetime probability distribution. *See* chapter 8 of the direct final rule TSD for further details.

7. Discount Rates

In the calculation of LCC, DOE applies discount rates appropriate to households to estimate the present value of future operating cost savings. DOE estimated a distribution of discount rates for consumer clothes dryers based on the opportunity cost of consumer funds.

DOE applies weighted average discount rates calculated from consumer debt and asset data, rather than marginal or implicit discount rates.[62] The LCC analysis estimates net present value over the lifetime of the product, so the appropriate discount rate will reflect the general opportunity cost of household funds, taking this time scale into account. Given the long-time horizon modeled in the LCC, the application of a marginal interest rate associated with an initial source of funds is inaccurate. Regardless of the method of purchase, consumers are expected to continue to rebalance their debt and asset holdings over the LCC analysis period, based on the restrictions consumers face in their debt payment requirements and the relative size of the interest rates available on debts and assets. DOE estimates the aggregate impact of this rebalancing using the historical distribution of debts and assets.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's triennial Survey of Consumer Finances[63] (''SCF'') starting in 1995 and ending in 2019. Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect. DOE assigned each sample household a specific discount rate drawn from one of the distributions. The average rate across all types of household debt and equity and income groups, weighted by the shares of each type, is 4.3 percent. *See* chapter 8 of the direct final rule TSD for further details on the development of consumer discount rates.

8. Energy Efficiency Distribution in the No-New-Standards Case

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of product efficiencies under the no-new-standards case (*i.e.,* the case without amended or new energy conservation standards).

To estimate the energy efficiency distribution of consumer clothes dryers for 2027 or 2028, DOE used 2021 model data from DOE's CCD and shipments data for consumer clothes dryers from the ENERGY STAR program.[64] [65] Based on the historical shipments trend of ENERGY STAR-qualified consumer clothes dryers, DOE estimated an annual 0.47-percent and 0.02-percent increase in shipment-weighted efficiency for electric standard and vented gas standard clothes dryers, respectively, beginning in 2021. Annual shipment-weighted efficiency for the other product classes (which in total have less than 2.5-percent market share) is held constant. The estimated market shares for the no-new-standards case for consumer clothes dryers are shown in Table IV.19 and Table IV.20. *See* chapter 8 of the direct final rule TSD for further information on the derivation of the efficiency distributions.

TABLE IV.19—NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION IN 2027 AND 2028: ELECTRIC STANDARD, ELECTRIC COMPACT (120V), ELECTRIC COMPACT (240V), AND VENTLESS ELECTRIC COMPACT (240V)

Electric standard		Electric compact (120V)		Vented electric compact (240V)		Ventless electric compact (240V)	
CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)
2.20	14	2.36	20	2.00	35	2.03	14

[62] The implicit discount rate is inferred from a consumer purchase decision between two otherwise identical goods with different first cost and operating cost. It is the interest rate that equates the increment of first cost to the difference in net present value of lifetime operating cost, incorporating the influence of several factors: transaction costs; risk premiums and response to uncertainty; time preferences; interest rates at which a consumer is able to borrow or lend. The implicit discount rate is not appropriate for the LCC analysis because it reflects a range of factors that influence consumer purchase decisions, rather than the opportunity cost of the funds that are used in purchases.

[63] U.S. Board of Governors of the Federal Reserve System. Survey of Consumer Finances. 1995, 1998, 2001, 2004, 2007, 2010, 2013, 2016, and 2019. Available at *www.federalreserve.gov/econresdata/scf/scfindex.htm* (last accessed May 2023).

[64] U.S. Department of Energy's Compliance Certification Database. Available at *www.regulations.doe.gov/certification-data/#q=Product_Group_s%3A** (last accessed April 17, 2023).

[65] ENERGY STAR, ENERGY STAR® Unit Shipment and Market Penetration Report Calendar Year 2021 Summary. Available at *www.energystar.gov/partner_resources/products_partner_resources/brand_owner_resources/unit_shipment_data* (last accessed April 17, 2023).

TABLE IV.19—NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION IN 2027 AND 2028: ELECTRIC STANDARD, ELECTRIC COMPACT (120V), ELECTRIC COMPACT (240V), AND VENTLESS ELECTRIC COMPACT (240V)—Continued

Electric standard		Electric compact (120V)		Vented electric compact (240V)		Ventless electric compact (240V)	
CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)
2.68	13	3.15	15	2.44	25	2.68	59
3.04	13	3.35	25	2.76	30	6.80	28
3.27	9	4.28	0	3.30	10		
3.93	42	4.33	0	3.57	0		
4.21	*6 (7)	4.63	0	3.82	0		
5.20	2	6.37	40	3.91	0		
7.39	1						

*The value in the parentheses indicates 2028 market share.

TABLE IV.20 NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION IN 2027 AND 2028: VENTED GAS STANDARD, AND VENTLESS ELECTRIC COMBINATION WASHER-DRYER*

Vented gas standard		Ventless electric, combination washer-dryer	
CEF_{D2} (lb/kWh)	Market share (%)	CEF_{D2} (lb/kWh)	Market share (%)
2.00	15	2.27	39
2.44	19	2.33	58
3.00	18	4.01	3
3.48	48		
3.83	0		

*There are no models or shipments data for vented gas compact clothes dryers on the market.

The LCC Monte Carlo simulations draw from the efficiency distributions and randomly assign an efficiency to the consumer clothes dryers purchased by each sample household in the no-new-standards case. The resulting percentage shares within the sample match the market shares in the efficiency distributions.

In the August 2022 NOPR, DOE performed a random assignment of efficiency levels to consumers in its Monte Carlo sample. While DOE acknowledges that economic factors may play a role when consumers decide on what type of clothes dryers to install, assignment of clothes dryer efficiency for a given installation, based solely on economic measures such as life-cycle cost or simple payback period, most likely would not fully and accurately reflect actual real-world installations. There are a number of market failures discussed in the economics literature that illustrate how purchasing decisions with respect to energy efficiency are unlikely to be perfectly correlated with energy use, as described below. DOE maintains that the method of assignment, is a reasonable approach, because it simulates behavior in the clothes dryer market, where market failures result in purchasing decisions not being perfectly aligned with economic interests, more realistically than relying only on apparent cost-effectiveness criteria derived from the limited information in RECS. DOE further emphasizes that its approach does not assume that all purchasers of consumer clothes dryers make economically irrational decisions (*i.e.,* the lack of a correlation is not the same as a negative correlation). As part of the random assignment, some homes with more frequent dryer events will be assigned higher efficiency clothes dryers, and some homes with particularly lower dryer events will be assigned baseline units. By using this approach, DOE acknowledges the uncertainty inherent in the data and minimizes any bias in the analysis by using random assignment, as opposed to assuming certain market conditions that are unsupported given the available evidence.

The following discussion provides more detail about the various market failures that affect consumer clothes dryer purchases. First, consumers are motivated by more than simple financial trade-offs. There are several behavioral factors that can influence the purchasing decisions of complicated multi-attribute products, such as consumer clothes dryers. For example, consumers (or decision makers in an organization) are highly influenced by choice architecture, defined as the framing of the decision, the surrounding circumstances of the purchase, the alternatives available, and how they are presented for any given choice scenario.[66] The same consumer or decision maker may make different choices depending on the characteristics of the decision context (*e.g.,* the timing of the purchase, competing demands for funds), which have nothing to do with the characteristics of the alternatives themselves or their prices. Consumers or decision makers also face a variety of other behavioral phenomena including loss aversion, sensitivity to information salience, and other forms of bounded rationality.[67] Thaler, who won the Nobel Prize in Economics in 2017 for his contributions to behavioral economics, and Sunstein point out that these behavioral factors are strongest when the decisions are complex and infrequent, when feedback on the decision is muted and slow, and when

[66] Thaler, R.H., Sunstein, C.R., and Balz, J.P. (2014). ''Choice Architecture'' in *The Behavioral Foundations of Public Policy,* Eldar Shafir (ed).

[67] Thaler, R.H., and Bernartzi, S. (2004). ''Save More Tomorrow: Using Behavioral Economics in Increase Employee Savings,'' *Journal of Political Economy* 112(1), S164–S187. *See* also Klemick, H., *et al.* (2015) ''Heavy-Duty Trucking and the Energy Efficiency Paradox: Evidence from Focus Groups and Interviews,'' *Transportation Research Part A: Policy & Practice,* 77, 154–166 (providing evidence that loss aversion and other market failures can affect otherwise profit-maximizing firms).

there is a high degree of information asymmetry.[68] These characteristics describe almost all purchasing situations of appliances and equipment, including consumer clothes dryers. The installation of a new or replacement consumer clothes dryers is done very infrequently, as evidenced by the mean lifetime of 14 years for consumer clothes dryers. Further, if the purchaser of the consumer clothes dryer is not the entity paying the energy costs (*e.g.,* a building owner and tenant), there may be little to no feedback on the purchase. Additionally, there are systematic market failures that are likely to contribute further complexity to how products are chosen by consumers, as explained in the following paragraphs. The first of these market failures—the split-incentive or principal-agent problem—is likely to significantly affect consumer clothes dryers. The principal-agent problem is a market failure that results when the consumer that purchases the equipment does not internalize all of the costs associated with operating the equipment. Instead, the user of the product, who has no control over the purchase decision, pays the operating costs. There is a high likelihood of split-incentive problems in the case of rental properties where the landlord makes the choice of what consumer clothes dryers to install, whereas the renter is responsible for paying energy bills.

In addition to the split-incentive problem, there are other market failures that are likely to affect the choice of consumer clothes dryer efficiency made by consumers. For example, unplanned replacements due to unexpected failure of equipment such as a consumer clothes dryer are strongly biased toward like-for-like replacement (*i.e.,* replacing the non-functioning equipment with a similar or identical product). Time is a constraining factor during unplanned replacements, and consumers may not consider the full range of available options on the market, despite their availability. The consideration of alternative product options is far more likely for planned replacements and installations in new construction.

Additionally, Davis and Metcalf[69] conducted an experiment demonstrating that, even when consumers are presented with energy consumption information, the nature of the information available to consumers (*e.g.,* from EnergyGuide labels) results in an inefficient allocation of energy efficiency across households with different usage levels. Their findings indicate that households are likely to make decisions regarding the efficiency of the air conditioning equipment of their homes that do not result in the highest net present value for their specific usage pattern (*i.e.,* their decision is based on imperfect information and, therefore, is not necessarily optimal). Also, most consumers did not properly understand the labels (specifically whether energy consumption and cost estimates were national averages or specific to their State). As such, consumers did not make the most informed decisions. Consumer clothes dryers do not require EnergyGuide labels, therefore energy consumption information is more difficult to determine for a consumer, resulting in an even more inefficient allocation of energy efficiency across households with different usage levels.

In part because of the way information is presented, and in part because of the way consumers process information, there is also a market failure consisting of a systematic bias in the perception of equipment energy usage, which can affect consumer choices. Attari *et al.*[70] show that consumers tend to underestimate the energy use of large energy-intensive appliances (such as air conditioners, dishwashers, and clothes dryers), but overestimate the energy use of small appliances (such as light bulbs). Therefore, it is possible that consumers systematically underestimate the energy use associated with consumer clothes dryers, resulting in less cost-effective purchases.

These market failures affect a sizeable share of the consumer population. A study by Houde[71] indicates that there is a significant subset of consumers that appear to purchase appliances without taking into account their energy efficiency and operating costs at all.

The existence of market failures in the residential sector is well supported by the economics literature and by a number of case studies. If DOE developed an efficiency distribution that assigned consumer clothes dryer efficiency in the no-new-standards case solely according to energy use or economic considerations such as life-cycle cost or payback period, the resulting distribution of efficiencies within the consumer sample would not reflect any of the market failures or behavioral factors above. Thus, DOE concludes such a distribution would not be representative of the consumer clothes dryer market. Further, even if a specific household is not subject to the market failures above, the purchasing decision of consumer clothes dryer efficiency can be highly complex and influenced by a number of factors (*e.g.,* aesthetics) not captured by the building characteristics available in the RECS sample. These factors can lead to households or building owners choosing a consumer clothes dryer efficiency that deviates from the efficiency predicted using only energy use or economic considerations such as life-cycle cost or payback period (as calculated using the information from RECS 2020).

There is a complex set of behavioral factors, with sometimes opposing effects, affecting the consumer clothes dryer market. It is impractical to model every consumer decision incorporating all of these effects at this extreme level of granularity given the limited available data. Given these myriad factors, DOE estimates the resulting distribution of such a model, if it were possible, would be very scattered with high variability. It is for this reason DOE utilizes a random distribution (after accounting for efficiency market share constraints) to approximate these effects. The methodology is not an assertion of economic irrationality, but instead, it is a methodological approximation of complex consumer behavior. The analysis is neither biased toward high or low energy savings. The methodology does not preferentially assign lower-efficiency consumer clothes dryers to households in the no-new-standards case where savings from the rule would be greatest, nor does it preferentially assign lower-efficiency consumer clothes dryers to households in the no-new-standards case where savings from the rule would be smallest. Some consumers were assigned the clothes dryers that they would have chosen if they had engaged in perfect economic considerations when purchasing the products. Others were assigned less-efficient clothes dryers even where a more-efficient product would eventually result in life-cycle savings, simulating scenarios where, for

[68] Thaler, R.H., and Sunstein, C.R. (2008). Nudge: Improving Decisions on Health, Wealth, and Happiness. New Haven, CT: Yale University Press.

[69] Davis, L.W., and G.E. Metcalf (2016): ''Does better information lead to better choices? Evidence from energy-efficiency labels,'' *Journal of the Association of Environmental and Resource Economists,* 3(3), 589–625. Available at: *www.journals.uchicago.edu/doi/full/10.1086/686252* (Last accessed August 1, 2023).

[70] Attari, S.Z., M.L. DeKay, C.I. Davidson, and W. Bruine de Bruin (2010): ''Public perceptions of energy consumption and savings.'' *Proceedings of the National Academy of Sciences* 107(37), 16054–16059. Available at: *www.pnas.org/content/107/37/16054* (Last accessed August 1, 2023).

[71] Houde, S. (2018): ''How Consumers Respond to Environmental Certification and the Value of Energy Information,'' *The RAND Journal of Economics,* 49 (2), 453–477. Available at: *onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12231* (Last accessed August 1, 2023).

example, various market failures prevent consumers from realizing those savings. Still others were assigned clothes dryers that were more efficient than one would expect simply from life-cycle costs analysis, reflecting, say, ''green'' behavior, whereby consumers ascribe independent value to minimizing harm to the environment.

Therefore, for this direct final rule, DOE performed a random assignment of efficiencies in the LCC analysis.

Additionally, for this direct final rule, DOE considered comments it received regarding the projected distribution of product efficiencies under the no-new-standards case that were submitted in response to the August 2022 NOPR. The CA IOUs requested that DOE clarify the changes in efficiency distributions from the 2021 preliminary analysis to the August 2022 NOPR analysis, specifically regarding the percentage of products that meet or exceed the ENERGY STAR level in the no-new-standards case. The CA IOUs stated that the preliminary analysis efficiency distributions resulted in a reasonably favorable consumer impact analysis for TSL 4. The CA IOUs recommended that DOE reconsider the analysis and conclusion regarding TSL 4 if the preliminary analysis efficiency distributions were more accurate. (CA IOUs, No. 50 at pp. 3–4).

In the 2021 preliminary analysis, DOE utilized a consumer-choice model to calculate market share of various efficiency options for consumer clothes dryers. This model considered factors such as the first cost for electric standard, vented gas standard, ventless electric compact (204V), and ventless electric washer-dryer units. The consumer-choice model relied on historical sales data from 2005 to 2011. To project the efficiency distribution for other product classes (electric compact (120V), vented electric compact (240V), DOE used inputs based on its own test samples and a review of models available in the market.

In the 2022 NOPR analysis, DOE evaluated concerns expressed by stakeholders regarding the adequacy and representativeness of the historical sales data from 2005 to 2011. DOE recognized that these data might not accurately reflect the correlations between shipments and sale prices in recent years. For this reason, as well as to maintain consistency in its methodology across product classes, DOE elected to use CCD model counts [72] instead of market shipments data to derive the no-new-standards case efficiency distributions for the NOPR.

The Joint Commenters commented that the ENERGY STAR shipment data is a better reflection of the consumer clothes dryer market than CCD model counts. The Joint Commenters stated that according to the ENERGY STAR shipment data, only about 40 percent of electric standard dryer models meet TSL 3 as opposed to DOE's estimate of 65 percent. (Joint Commenters, No. 51 at pp. 3–4).

For this direct final rule, DOE has considered the ENERGY STAR shipment data for standard consumer clothes dryers along with other pertinent market information. As a result, DOE has revised the market share estimate for electric and gas standard consumer clothes dryers meeting ENERGY STAR criteria in the compliance year. DOE reduced market share of electric standard consumer clothes dryers that meet TSL 3 from 61 percent to 42 percent and increased market share of gas standard consumer clothes dryers that meet TSL 3 from 38 percent to 48 percent. For the remaining product classes, which together account for less than 2.5 percent of the total shipments, DOE has continued to use the CCD model counts because it is not aware of other available information.

9. Payback Period Analysis

The payback period is the amount of time (expressed in years) it takes the consumer to recover the additional installed cost of more efficient products, compared to baseline products, through energy cost savings. Payback periods that exceed the life of the product mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficiency level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. DOE refers to this as a ''simple PBP'' because it does not consider changes over time in operating cost savings. The PBP calculation uses the same inputs as the LCC analysis when deriving first-year operating costs.

As noted previously, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficiency level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure and multiplying those savings by the average energy price projection for the year in which compliance with the amended standards would be required.

G. Shipments Analysis

DOE uses projections of annual product shipments to calculate the national impacts of potential amended or new energy conservation standards on energy use, NPV, and future manufacturer cash flows.[73] The shipments model takes an accounting approach, tracking market shares of each product class and the vintage of units in the stock. Stock accounting uses product shipments as inputs to estimate the age distribution of in-service product stocks for all years. The age distribution of in-service product stocks is a key input to calculations of both the NES and NPV, because operating costs for any year depend on the age distribution of the stock.

Total product shipments for consumer clothes dryers are developed by considering the demand from replacements for units in stock that fail and the demand from new installations in newly constructed homes. DOE calculated shipments due to replacements using the retirement function developed for the LCC analysis. DOE calculated shipments due to new installations using estimates for consumer clothes dryer saturation rates in newly constructed homes from 2015 to 2020 in the 2020 RECS and projections of new housing starts in *AEO2023*.

DOE disaggregated total product shipments into each product class using estimated market shares of each product class. To estimate these market shares, DOE first developed a linear time series regression model to estimate market share between the product fuel type (*i.e.,* gas or electric) by fitting the historical shipments of gas consumer clothes dryers. Historical shipments data showed a steady decline of market share of gas consumer clothes dryers, from 23 percent in 2000 to 17 percent in 2022. The linear regression model indicates that market share of gas

[72] The CCD database lists basic models of certified consumer clothes dryers that are subject to DOE's energy conservation standards, including their rated capacities and CEF. These clothes dryer models are submitted by manufacturers or their third-party representatives.

[73] DOE uses data on manufacturer shipments as a proxy for national sales, as aggregate data on sales are lacking. In general, one would expect a close correspondence between shipments and sales.

consumer clothes dryers is strongly correlated with its historical time series.

After developing the market share estimation between electric and gas consumer clothes dryers, DOE then subtracted the estimated gas clothes dryer market share from total shipments and divided the electric clothes dryer market share into each electric consumer clothes dryer product class. DOE estimated that electric standard and vented gas standard consumer clothes dryers account for approximately 84 percent and 14 percent of the total shipments during the analysis period, respectively.

To estimate shipments under a standards case, DOE considers the impacts on shipments from changes in product purchase price and operating cost associated with higher energy efficiency levels using a price elasticity and an efficiency elasticity. As in the April 2021 preliminary analysis, DOE employed an efficiency elasticity rate of 0.2 percent and a price elasticity rate of −0.45 percent in its shipments model. These values are based on analysis of aggregated data for five residential appliances: consumer clothes washers, dishwashers, refrigerators, freezers, and room air conditioners.[74] The market impact is defined as the difference between the product of price elasticity of demand and the change in price due to a standard level, and the product of the efficiency elasticity and the change in operating costs due to a standard level.

DOE assumed when market impact occurs (*i.e.,* when shipments drop under a standards case), the affected consumers would either repair their product or purchase a used clothes dryer rather than a new one. In the repair scenario, the model assumes that the product's life is extended by approximately 5 years. In the used product scenario, the model assumes the remaining average lifetime for a used clothes dryer is 7 years. Therefore, this market impact effectively influences the decision between repairing or replacing the product, as well as the decision between purchasing a used dryer or a new one. *See* chapter 9 of the direct final rule TSD for details.

For this direct final rule, DOE considered comments it received regarding the shipments analysis that were submitted in response to the August 2022 NOPR. Whirlpool commented that consumers may continue replacing cheaper components well into the life of an electromechanical controlled dryer, extending its life, while they may not decide to make a more expensive electronic component repair, like a user interface assembly, after several years of ownership of an electronic control dryer. Whirlpool stated that DOE's proposed standards may effectively shorten the useful life of a consumer clothes dryer because of this repair-versus-replacement calculus, resulting in loss of time-saving benefits of dryer ownership. (Whirlpool, No. 53 at pp. 8–9)

As stated in section IV.C.1 of this document, the recommended standards would continue to allow for electromechanical controlled clothes dryers to be sold on the market. In addition, DOE is not aware of reliability issues associated with the implementation of electronic controls relative to electromechanical controls. Whirlpool's assertion that the adopted standards may shorten the useful life of consumer clothes dryers lacks quantitative data to support it. As stated in section IV.F.6 of this document, DOE's lifetime estimation is calibrated using shipments data, which include the adopted efficiency levels of ENERGY STAR-qualified consumer clothes dryers sold in the market. DOE's updated Weibull lifetime distribution in this direct final rule captures the trend of shorter lifetime and delayed replacement of consumer clothes dryers based on the recent field data. *See* chapter 9 of the direct final rule TSD for details.

H. National Impact Analysis

The NIA assesses the NES and the NPV from a national perspective of total consumer costs and savings that would be expected to result from new or amended standards at specific efficiency levels.[75] (''Consumer'' in this context refers to consumers of the product being regulated.) DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual product shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses. For the present analysis, DOE projected the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of consumer clothes dryers sold from 2027 through 2056 for all TSLs other than 2028 through 2057 for TSL 3 (the Recommended TSL detailed in the Joint Agreement).

DOE evaluates the impacts of new or amended standards by comparing a case without such standards with standards-case projections. The no-new-standards case characterizes energy use and consumer costs for each product class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each product class if DOE adopted new or amended standards at specific energy efficiency levels (*i.e.,* the TSLs or standards cases) for that class. For the standards cases, DOE considers how a given standard would likely affect the market shares of products with efficiencies greater than the standard.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.21 summarizes the inputs and methods DOE used for the NIA analysis for the direct final rule. Discussion of these inputs and methods follows the table. *See* chapter 10 of the direct final rule TSD for further details.

TABLE IV.21—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS

Inputs	Methods
Shipments	Annual shipments from shipments model.
Compliance Date of Standard	TSL 1, TSL 2, TSL 4, TSL 5, and TSL 6: 2027. TSL 3 (the Recommended TSL): 2028.

[74] Fujita, K. (2015) Estimating Price Elasticity using Market-Level Appliance Data. Lawrence Berkeley National Laboratory, LBNL–188289.

[75] The NIA accounts for impacts in the 50 states and U.S. territories.

TABLE IV.21—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS—Continued

Inputs	Methods
Efficiency Trends	No-new-standards case: Annual efficiency improvement of 0.47% for electric standard and 0.02% for vented gas standard consumer clothes dryers. Standards cases: ''Roll-up'' equipment to meet potential efficiency level.
Annual Energy Consumption per Unit.	Annual weighted average values are a function of energy use at each TSL.
Total Installed Cost per Unit	Annual weighted average values are a function of cost at each TSL. Incorporates projection of future product prices based on historical data.
Annual Energy Cost per Unit	Annual weighted average values as a function of the annual energy consumption per-unit and energy prices.
Repair and Maintenance Cost per Unit.	Annual values change between electromechanical controls and electronic controls efficiency level.
Energy Price Trends	*AEO2023* projections (to 2050) and constant value based on the average between 2046 and 2050 thereafter.
Energy Site-to-Primary and FFC Conversion.	A time-series conversion factor based on *AEO2023.*
Discount Rate	3% and 7%.
Present Year	2024.

1. Product Efficiency Trends

A key component of the NIA is the trend in energy efficiency projected for the no-new-standards case and each of the standards cases. Section IV.F.8 of this document describes how DOE developed an energy efficiency distribution for the no-new-standards case (which yields a shipment-weighted average efficiency) for each of the considered product classes for the year of anticipated compliance with an amended or new standard. To project the trend in efficiency absent amended standards for consumer clothes dryers over the entire shipments projection period, DOE used an annual 0.47-percent and 0.02-percent increase in shipment-weighted efficiency beginning in 2021 for electric standard and vented gas standard consumer clothes dryers, respectively. The efficiency for the other product classes remains at their 2021 shipments-weighted efficiency levels. The approach is further described in chapter 10 of the direct final rule TSD.

For the standards cases, DOE used a ''roll-up'' scenario to establish the shipment-weighted efficiency for the year that standards are assumed to become effective. In this scenario, the market shares of products in the no-new-standards case that do not meet the standard under consideration would ''roll-up'' to meet the new standard level, and the market share of products above the standard would remain unchanged.

2. National Energy Savings

The national energy savings analysis involves a comparison of national energy consumption of the considered products between each potential standards case (TSL) and the case with no-new or amended energy conservation standards. DOE calculated the national energy consumption by multiplying the number of units (stock) of each product (by vintage or age) by the unit energy consumption (also by vintage). DOE calculated annual NES based on the difference in national energy consumption for the no-new-standards case and for each higher efficiency standard case. DOE estimated energy consumption and savings based on-site energy and converted the electricity consumption and savings to primary energy (*i.e.,* the energy consumed by power plants to generate site electricity) using annual conversion factors derived from *AEO2023.* Cumulative energy savings are the sum of the NES for each year over the timeframe of the analysis.

Use of higher efficiency products is sometimes associated with a direct rebound effect, which refers to an increase in utilization of the product due to the increase in efficiency. DOE did not find any data on the rebound effect specific to consumer clothes dryers, so it did not include a rebound effect in the analysis.

Separate from a direct rebound effect, DOE also assessed the potential implications of amended standards as it relates to clothes dryer energy use, namely whether amended standards could result in a decrease in drying performance that would require consumers to re-run their drying cycles to achieve satisfactory drying performance. As discussed in section II.B.2 of this document, DOE's appendix D2 test procedure includes a maximum FMC threshold (*i.e.,* a dryness level threshold that much be achieved in order to be considered a valid test cycle), which ensures that the rated energy consumption of clothes dryers is representative of consumer expectations for dryness. DOE testing confirmed that commercially available products achieve this FMC dryness threshold at each of the efficiency levels considered in this direct final rule analysis. Consequently, DOE has determined that clothes dryers that comply with the amended standards will provide consumer-acceptable levels of dryness corresponding to the rated energy consumption as measured by appendix D2. In the NES, therefore, DOE assumed that the amended standards would not result in any increase in clothes dryer usage, such as that arising from consumers re-running drying cycles.

In 2011, in response to the recommendations of a committee on ''Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards'' appointed by the National Academy of Sciences, DOE announced its intention to use FFC measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (Aug. 18, 2011). After evaluating the approaches discussed in the August 18, 2011, notice, DOE published a statement of amended policy in which DOE explained its determination that EIA's National Energy Modeling System (''NEMS'') is the most appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (Aug. 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector [76] that EIA uses to prepare its *Annual Energy Outlook.* The FFC factors incorporate losses in production and delivery in the case of natural gas

[76] For more information on NEMS, refer to *The National Energy Modeling System: An Overview 2009,* DOE/EIA–0581(2009), October 2009. Available at *www.eia.gov/forecasts/aeo/index.cfm* (last accessed April 20, 2023).

(including fugitive emissions) and additional energy used to produce and deliver the various fuels used by power plants. The approach used for deriving FFC measures of energy use and emissions is described in appendix 10B of the direct final rule TSD.

For this direct final rule, DOE considered comments it had received regarding the methodology for calculating the national energy savings that was presented in the August 2022 NOPR. The approach used for this direct final rule is largely the same approach DOE had used for the August 2022 NOPR analysis.

In response to the August 2022 NOPR, EEI stated that in the past, DOE stated potentially using a captured-energy approach when estimating upstream full-fuel-cycle energy savings; however, EEI noted that in recent notices and rulemakings, DOE is now overstating these estimates by using a fossil fuel equivalent for renewable energy, significantly overstating the upstream savings. (EEI, No. 37 at pp. 45–46)

As previously mentioned, DOE converts electricity consumption and savings to primary energy and FFC energy using annual conversion factors derived from the *AEO.* Traditionally, EIA has used the fossil fuel equivalency approach to report noncombustible renewables' contribution to total primary energy. The fossil fuel equivalency approach applies an annualized weighted average heat rate for fossil fuel power plants to the electricity generated (in kWh) from noncombustible renewables. EIA recognizes that using captured energy (*i.e.,* the net energy available for direct consumption after transformation of a noncombustible renewable energy into electricity) and using incident energy (*i.e.,* the mechanical, radiation, or thermal energy that is measurable as the ''input'' to the device) are possible approaches for converting renewable electricity to a common measure of primary energy, but it continues to use the fossil fuel equivalency approach in the *AEO* and other reporting of energy statistics. DOE has used this approach to accounting for primary energy savings from energy efficiency standards for the entirety of the appliance standards program.

Whirlpool commented that the lessening of utility and performance of dryers, including increases to drying cycle times and potentially increased fabric damage to clothes, may lead to corresponding compensatory behavioral changes from consumers that may result in lost energy savings. Whirlpool recommended that DOE's analysis account for possible negative rebound effects of changes, such that the expected energy savings from an amended standard may not be fully delivered over the analyzed period. Whirlpool commented that consumers associate longer drying times with more potential damage to their clothes and may choose cycles or options that reduce overall drying time at the expense of energy consumption. (Whirlpool, No. 53 at p. 6)

DOE has examined the potential impacts on different attributes of product performance while considering amended standards, as detailed in section IV.C.1 of this document. As discussed further in section V.B.4 of this document, DOE data indicate that the standards adopted by this direct final rule will not necessitate any substantive increase in cycle times compared to typical cycle times currently associated with baseline consumer clothes dryers and therefore are not expected to have any negative impacts on fabric care and product wear and tear that would lead consumers to use more energy consumptive drying cycles. Moreover, DOE notes that the appendix D2 test procedure, which will be required to demonstrate compliance with the amended standards established in this direct final rule, and is currently required for ENERGY STAR certification, ensures that clothes dryers provide a consumer-acceptable level of dryness.

Furthermore, as previously discussed, on February 14, 2024, DOE received a second joint statement from the same group of stakeholders that submitted the Joint Agreement (including AHAM, of which Whirlpool is a member) in which the signatories reaffirmed the standards recommended in the Joint Agreement.[77] In particular, the letter states that the stakeholders do not anticipate the recommended standards will negatively affect features or performance, including cycle time. In particular, the signatories stated that because the test procedure that will be used to determine compliance with amended standards (*i.e.,* appendix D2) requires that dryers meet a threshold for ''final moisture content'' in order to be certified as compliant, this final moisture content requirement ensures that compliant clothes dryers will adequately dry clothes. The signatories further noted that there are more than 400 electric clothes dryer models and nearly 200 gas clothes dryer models that are certified to the current ENERGY STAR specification, which is equivalent to the recommended standard levels and is based on appendix D2, and that these models all meet the final moisture content threshold specified in appendix D2. For further discussion of consumer clothes dryer performance as it relates to amended standards, see section V.B.4 of this document.

DOE acknowledges that this conclusion is contrary to its assumptions in the final rule that it published on December 16, 2020 (''December 2020 Final Rule''). 85 FR 81359. There, DOE assumed that consumers might need to re-run their clothes washers or dryers through multiple cycles ''to adequately clean or dry their clothing.'' 85 FR 81365. In this rulemaking, DOE has found no evidence suggesting that consumers are running their dryers multiple times at TSL 3 (*i.e.,* the Recommended TSL), which corresponds to the current ENERGY STAR efficiency level for both electric and gas standard clothes dryers. As supported by data described in section IV.E of this document, average consumer usage of electric standard clothes has steadily declined from 301 cycles per year per dryer in the 2005 RECS to 213 cycles per year per dryer in the 2020 RECS, and vented gas standard clothes dryer usage has declined from 292 cycles in the 2005 RECS to 213 cycles in the 2020 RECS, while the average household size has remained essentially unchanged (average 3 household members) during the same period. This shows a significant downward trend in the average number of cycles run on each consumer clothes dryer over the past 15 years, even after the implementation of the current amended standard in 2015. These data indicate that amended energy conservation standards have not resulted in consumers increasing dryer usage due to amended standards for consumer clothes dryers.

Given that there is no evidence of any previous consumer clothes dryer standard increasing drying cycles per year, and in fact, instead cycles per year have decreased over time through multiple standards, DOE determines that a standard at the Recommended TSL would not be expected to lead consumers to increase their use of consumer clothes dryers.

3. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are (1) total annual installed cost, (2) total annual operating costs (energy costs and repair and maintenance costs), and (3) a discount factor to calculate the present value of costs and savings. DOE

[77] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058.*

calculates net savings each year as the difference between the no-new-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating cost savings over the lifetime of each product shipped during the projection period.

As discussed in section IV.F.1 of this document, DOE developed consumer clothes dryer price trends based on historical PPI data. DOE applied the same trends to project prices for each product class at each considered efficiency level. By 2057, which is the end date of the projection period for the Recommended TSL detailed in Joint Agreement, the average consumer clothes dryer (real) price is projected to drop 18 percent relative to 2022. DOE's projection of product prices is described in appendix 10C of the direct final rule TSD.

To evaluate the effect of uncertainty regarding the price trend estimates, DOE investigated the impact of different product price projections on the consumer NPV for the considered TSLs for consumer clothes dryers. In addition to the default price trend, DOE considered two product price sensitivity cases: (1) a high-price-decline case based on the combined price index from 1980 to 2022 [78] and (2) a constant price trend at the 2022 value. The derivation of these price trends and the results of these sensitivity cases are described in appendix 10C of the direct final rule TSD.

The energy cost savings are calculated using the estimated energy savings in each year and the projected price of the appropriate form of energy. To estimate energy prices in future years, DOE multiplied the average national energy prices by the projection of annual national-average residential energy price changes in the Reference case from *AEO2023,* which has an end year of 2050. To estimate price trends after 2050, the 2046–2050 average was used for all years. As part of the NIA, DOE also analyzed scenarios that used inputs from variants of the *AEO2023* Reference case that have lower and higher economic growth. Those cases have lower and higher energy price trends compared to the Reference case. NIA results based on these cases are presented in appendix 10D of the direct final rule TSD.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this direct final rule, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the OMB to Federal agencies on the development of regulatory analysis.[79] The discount rates for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the ''social rate of time preference,'' which is the rate at which society discounts future consumption flows to their present value.

I. Consumer Subgroup Analysis

In analyzing the potential impact of new or amended energy conservation standards on consumers, DOE evaluates the impact on identifiable subgroups of consumers that may be disproportionately affected by a new or amended national standard. The purpose of a subgroup analysis is to determine the extent of any such disproportional impacts. DOE evaluates impacts on particular subgroups of consumers by analyzing the LCC impacts and PBP for those particular consumers from alternative standard levels. For this direct final rule, DOE analyzed the impacts of the considered standard levels on two subgroups: (1) low-income households and (2) senior-only households. The analysis used subsets of the 2020 RECS sample composed of households that meet the criteria for the considered subgroups. DOE used the LCC and PBP spreadsheet model to estimate the impacts of the considered efficiency levels on these subgroups. Chapter 11 in the direct final rule TSD describes the consumer subgroup analysis.

For this direct final rule, DOE considered comments it received regarding the consumer subgroup analysis that were submitted in response to the August 2022 NOPR. DOE notes that although several of the comments discussed below are from AHAM, as previously discussed, on February 14, 2024, DOE received a second joint statement from the same group of stakeholders that submitted the Joint Agreement (including AHAM) in which the signatories reaffirmed the standards recommended in the Joint Agreement.[80] In particular, the letter states that ''the recommended standards represent the maximum levels of efficiency that are technologically feasible and *economically justified*.'' (emphasis added).

In response to the August 2022 NOPR, AHAM stated that in a recent consumer study conducted by Bellomy Research for AHAM, low-income households were at a disadvantage when purchasing or replacing a laundry appliance, with many households indicating that they would have to make financial sacrifices in other areas of their lives to accommodate purchasing a dryer. AHAM stated that over 90 percent of low-income households cited cost as the most important factor when deciding to purchase a dryer, and nearly 75 percent of low-income households indicated they would not be willing to pay around $100 more for a more efficient appliance at the time of purchase to save approximately $50–$150 in energy costs over the lifetime of that appliance. AHAM stated that one in four low-income households indicated they would delay a replacement purchase if their laundry appliance stopped working, and in cases of replacement, they would replace it with another entry-level/value-tier model. Additionally, AHAM stated that over half of low-income households indicated they would turn to purchasing a used dryer or apply for assistance. (AHAM, No. 46 at pp. 6–7). AHAM stated that standards that result in increased prices for entry-level appliances or that price some consumers out of the clothes dryer market by eliminating technology options that allow manufacturers to produce entry-level models (*e.g.,* electromechanical controls) deepen inequity for underserved communities. According to AHAM, if low-income consumers do not have equitable access, they may forego dryer ownership and use a laundromat with lost time savings and additional operating costs, rely on expensive financing options, or buy an older and possibly less efficient used dryer, thus reducing overall savings potential. (AHAM, No. 46 at pp. 5–6, 8)

AGA and APGA supported AHAM's comments on the disproportionate effect more stringent standards could have on low-income consumers. (AGA et al., No. 47 at p. 4)

Whirlpool stated that low-income consumers may not be able to purchase more efficient dryers due to the

[78] DOE combined PPI data of ''household laundry equipment'' from 1948 to 2016 and PPI data of ''major household appliance: primary products'' from 2016 to 2022 into one time-series price index to project future price for consumer clothes dryers.

[79] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* Available at *www.whitehouse.gov/omb/information-for-agencies/circulars/* (last accessed April 20, 2023). DOE used the prior version of Circular A–4 (2003) as a result of the effective date of the new version.

[80] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058.*

significant cost increase and their inability to pay for very large emergency purchases over $500. Whirlpool stated that while there may be some level of life-cycle cost savings from proposed standards, consumers who can no longer afford an entry-level dryer may never realize these savings. Whirlpool stated that purchase price increases driven by DOE's proposed standards may drive undesirable consumer behavior, including repairing the old dryer or purchasing a used dryer, effectively keeping older and less efficient appliances on the grid. Whirlpool requested that DOE ensure new appliances remain as affordable to low-income consumers as possible. (Whirlpool, No. 53 at pp. 7–8)

NYSERDA stated that amended standards would significantly improve energy outcomes for low-income households and not create additional burdens. NYSERDA stated that in New York, there is a relatively even split between owner-occupied and rented homes, with a significant number of rental properties, especially in new construction, having in-unit consumer clothes dryers. NYSERDA commented that for individual renters who are not responsible for the purchase of their clothes dryer but who are responsible for paying their utility bills, amended standards will provide utility bill savings without incurring direct equipment costs. (NYSERDA, No. 48 at p. 2)

According to the 2020 RECS clothes dryer sample, approximately 47 percent of low-income households who have a dryer are renters. In most cases, the property owner would purchase a new dryer. While the owner might seek to collect some of this cost in rent, the ability to do so is constrained by lease agreements and larger market forces that influence rent levels in particular locations. Thus, it is reasonable to conclude that renters would see a significant net benefit from a higher efficiency dryer, and this is seen in the results of DOE's analysis (*see* section V.B.1.b of this document for results of the consumer subgroup analysis). Additionally, for this direct final rule, DOE implemented a scenario assuming that landlords would pass some of the incremental clothes dryer costs to renters in the LCC analysis. The results indicate that this scenario would not impact DOE's decision on adopting the amended standards. For details of the sensitivity results, *see* appendix 11A of the direct final rule TSD.

In DOE's analysis, approximately 53 percent of low-income households who have a dryer are homeowners, who would be responsible for purchasing a new dryer. Given that the average incremental increase in price for a dryer meeting the adopted standards (relative to the baseline model that reflects current entry-level products) is $27, DOE believes it is reasonable to conclude that most low-income homeowners who could afford to purchase a new dryer under the current standard could also afford to purchase a dryer that meets the new standard, particularly in the absence of data indicating otherwise. Furthermore, DOE's analysis found that for the largest product class (*i.e.,* electric standard), less than 1 percent of low-income households would experience a net cost under the adopted standard, but the majority would see a net benefit (*see* section V.B.1.b of this document for results of the consumer subgroup analysis).

In total, DOE's analysis estimated that 45 percent of low-income households who have a dryer would experience a net benefit and 54 percent of low-income households who have a dryer would have no impact under the adopted standard.

AHAM comment in response to the August 2022 NOPR that low-income consumers might lose equitable access to on-site dryer usage because of the amended standards did not include supporting data so DOE was unable to fully evaluate the assertion. Nevertheless, DOE's shipments analysis takes into account the market impact under a standards case. For this direct final rule, DOE has implemented scenarios in which affected consumers would either repair their clothes dryers or opt to purchase a used one instead of a new clothes dryer (*see* section IV.G of this document).

AHAM recommended that DOE review all available data sources regarding low-income households and appliances to incorporate into its low-income analysis, in particular the basis of only differential discount rates. AHAM commented that DOE's analysis is a very myopic view of the effects of standards on low-income households, and within this framework the approach of using average discount rates is fundamentally flawed in its understanding of the relationship between disposable income and balance sheet rebalancing. (AHAM, No. 46 at p. 8)

DOE's approach to the low-income consumer subgroup analysis includes households that do not have assets or debts included in the SCF. It is likely that a majority of these ''unbanked'' households primarily rely on cash to complete transactions and as a form of savings, which is included in the distribution of discount rates associated with low-income consumers. Consumers that rely entirely on cash are assigned a discount rate of 0 percent, as there is no lost opportunity cost from alternative noncash assets or debts. For households that utilize nontraditional, nonbank financing, DOE's methodology includes a distribution of high discount rates (*i.e.,* >10% percent), which are representative of the opportunity cost associated with nonbank lines of credit. Therefore, DOE determined that this comprehensive approach enables a fair assessment of discount rates for low-income consumers who have different financial situations.

J. Manufacturer Impact Analysis

1. Overview

DOE performed an MIA to estimate the financial impacts of amended energy conservation standards on manufacturers of consumer clothes dryers and to estimate the potential impacts of such standards on direct employment and manufacturing capacity. The MIA has both quantitative and qualitative aspects and includes analyses of projected industry cash flows, the INPV, investments in research and development (''R&D'') and manufacturing capital, and domestic manufacturing employment. Additionally, the MIA seeks to determine how amended energy conservation standards might affect manufacturing employment, capacity, and competition, as well as how standards contribute to overall regulatory burden. Finally, the MIA serves to identify any disproportionate impacts on manufacturer subgroups, including small business manufacturers.

The quantitative part of the MIA primarily relies on the GRIM, an industry cash flow model with inputs specific to this rulemaking. The key GRIM inputs include data on the industry cost structure, unit production costs, product shipments, manufacturer markups, and investments in R&D and manufacturing capital required to produce compliant products. The key GRIM outputs are the INPV, which is the sum of industry annual cash flows over the analysis period, discounted using the industry-weighted average cost of capital, and the impact on domestic manufacturing employment. The model uses standard accounting principles to estimate the impacts of more stringent energy conservation standards on a given industry by comparing changes in INPV and domestic manufacturing employment between a no-new-standards case and the various standards cases. To capture

the uncertainty relating to manufacturer pricing strategies following amended standards, the GRIM estimates a range of possible impacts under different markup scenarios.

The qualitative part of the MIA addresses manufacturer characteristics and market trends. Specifically, the MIA considers such factors as a potential standard's impact on manufacturing capacity, competition within the industry, the cumulative impact of other DOE and non-DOE regulations, and impacts on manufacturer subgroups. The complete MIA is outlined in chapter 12 of the direct final rule TSD.

DOE conducted the MIA for this rulemaking in three phases. In Phase 1 of the MIA, DOE prepared a profile of the consumer clothes dryer manufacturing industry based on the market and technology assessment, preliminary manufacturer interviews, and publicly available information. This included a top-down analysis of consumer clothes dryer manufacturers that DOE used to derive preliminary financial inputs for the GRIM (*e.g.,* revenues; materials, labor, overhead, and depreciation expenses; selling, general, and administrative expenses (''SG&A''); and R&D expenses). DOE also used public sources of information to further calibrate its initial characterization of the consumer clothes dryer manufacturing industry, including company filings of form 10–K from the SEC,[81] corporate annual reports, the U.S. Census Bureau's Quarterly Survey of Plant Capacity Utilization,[82] the U.S. Census Bureau's Annual Survey of Manufactures (''ASM''),[83] and reports from Dun & Bradstreet.[84]

In Phase 2 of the MIA, DOE prepared a framework industry cash-flow analysis to quantify the potential impacts of amended energy conservation standards. The GRIM uses several factors to determine a series of annual cash flows starting with the announcement of the standard and extending over a 30-year period following the compliance date of the standard. These factors include annual expected revenues, costs of sales, SG&A and R&D expenses, taxes, and capital expenditures. In general, energy conservation standards can affect manufacturer cash flow in three distinct ways: (1) creating a need for increased investment, (2) raising production costs per-unit, and (3) altering revenue due to higher per-unit prices and changes in sales volumes.

In addition, during Phase 2, DOE developed interview guides to distribute to manufacturers of consumer clothes dryers in order to develop other key GRIM inputs, including product and capital conversion costs, and to gather additional information on the anticipated effects of energy conservation standards on revenues, direct employment, capital assets, industry competitiveness, and subgroup impacts.

In Phase 3 of the MIA, DOE conducted structured, detailed interviews with representative manufacturers. During these interviews, DOE discussed engineering, manufacturing, procurement, and financial topics to validate assumptions used in the GRIM and to identify key issues or concerns. As part of Phase 3, DOE also evaluated subgroups of manufacturers that may be disproportionately impacted by amended standards or that may not be accurately represented by the average cost assumptions used to develop the industry cash flow analysis. Such manufacturer subgroups may include small business manufacturers, low-volume manufacturers, niche players, and/or manufacturers exhibiting a cost structure that largely differs from the industry average. DOE identified one subgroup for a separate impact analysis: small business manufacturers. The small business subgroup is discussed in chapter 12 of the direct final rule TSD.

2. Government Regulatory Impact Model and Key Inputs

DOE uses the GRIM to quantify the changes in cash flow due to amended standards that result in a higher or lower industry value. The GRIM uses a standard, annual discounted cash-flow analysis that incorporates manufacturer costs, manufacturer markups, shipments, and industry financial information as inputs. The GRIM models changes in costs, distribution of shipments, investments, and manufacturer margins that could result from an amended energy conservation standard. The GRIM spreadsheet uses the inputs to arrive at a series of annual cash flows, beginning in 2024 (the base year of the analysis) and continuing 30 years from the analyzed compliance year.[85] DOE calculated INPVs by summing the stream of annual discounted cash flows during this period. For manufacturers of consumer clothes dryers, DOE used a real discount rate of 7.5 percent, which was derived from industry financials and then modified according to feedback received during manufacturer interviews.

The GRIM calculates cash flows using standard accounting principles and compares changes in INPV between the no-new-standards case and each standards case. The difference in INPV between the no-new-standards case and a standards case represents the financial impact of the amended energy conservation standard on manufacturers. As discussed previously, DOE developed the critical GRIM inputs using a number of sources, including publicly available data, results of the engineering analysis and shipments analysis, and information gathered from industry stakeholders during the course of manufacturer interviews. The GRIM results are presented in section V.B.2 of this document. Additional details about the GRIM, the discount rate, and other financial parameters can be found in chapter 12 of the direct final rule TSD.

a. Manufacturer Production Costs

Manufacturing more efficient products is typically more expensive than manufacturing baseline products due to the use of more complex components, which are typically more costly than baseline components. The changes in MPCs of covered products can affect the revenues, gross margins, and cash flow of the industry. DOE models the relationship between efficiency and MPCs as a part of its engineering analysis. For a complete description of the MPCs, *see* section IV.C of this document and chapter 5 of the direct final rule TSD.

b. Shipments Projections

The GRIM estimates manufacturer revenues based on total unit shipment projections and the distribution of those shipments by efficiency level. Changes in sales volumes and efficiency mix over time can significantly affect manufacturer finances. For this analysis, the GRIM uses the NIA's annual shipment projections derived from the shipments analysis from the base year (2024) to the end year of the analysis period (30 years from the analyzed compliance date [86]). *See* section IV.G of

[81] U.S. Securities and Exchange Commission. Company Filings. Available at *www.sec.gov/edgar/searchedgar/companysearch.html.* (Last accessed June 6, 2023).

[82] U.S. Census Bureau. Quarterly Survey of Plant Capacity Utilization. Available at *www.census.gov/programs-surveys/qpc/data/tables.html* (last accessed June 1, 2023).

[83] U.S. Census Bureau, Annual Survey of Manufactures. Available at *www.census.gov/programs-surveys/asm/data/tables.html* (last accessed June 1, 2023).

[84] The Dun & Bradstreet subscription login is available at *app.dnbhoovers.com* (last accessed June 8, 2023).

[85] For the no-new-standards case and all TSLs except the Recommended TSL (*i.e.,* TSL 3), the analysis period ranges from 2024–2056. For the Recommended TSL, the analysis period ranges from 2024–2057.

[86] *Id.*

this document and chapter 9 of the direct final rule TSD for additional details.

c. Capital and Product Conversion Costs

Amended energy conservation standards could cause manufacturers to incur conversion costs to bring their production facilities and product designs into compliance. DOE evaluated the level of conversion-related expenditures that would be needed to comply with each considered efficiency level in each product class. For the MIA, DOE classified these conversion costs into two major groups: (1) capital conversion costs and (2) product conversion costs. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new compliant product designs can be fabricated and assembled. Product conversion costs are investments in research, development, testing, marketing, and other non-capitalized costs necessary to make product designs comply with amended energy conservation standards.

DOE relied on manufacturer feedback to evaluate the level of capital and product conversion costs manufacturers would likely incur at the various TSLs. During confidential interviews, DOE asked manufacturers to estimate the capital conversion costs (*e.g.,* changes in production processes, equipment, and tooling) to meet the various efficiency levels. DOE also asked manufacturers to estimate the redesign effort and engineering resources required at various efficiency levels to quantify the product conversion costs. Based on manufacturer feedback, DOE also estimated ''re-flooring'' costs associated with replacing obsolete display models in big-box stores (*e.g.,* Lowe's, Home Depot, Best Buy) due to higher standards. Some manufacturers stated that with a new product release, big-box retailers discount outdated display models, and manufacturers share any losses associated with discounting the retail price. The estimated re-flooring costs for each efficiency level were incorporated into the product conversion cost estimates, as DOE modeled the re-flooring costs as a marketing expense.

DOE reviewed the DOE CCD,[87] U.S. market share estimates, and company characteristics to scale the company-specific conversion cost estimates to levels that represent the overall industry. First, DOE used data from its CCD,[88] the ENERGY STAR-qualified product database,[89] and the California Energy Commission database [90] to identify original equipment manufacturers (''OEMs'') of the covered products. Next, DOE assessed each OEM's U.S. market share and product profile (*e.g.,* estimated sales by product class and efficiency) for consumer clothes dryers. Finally, DOE estimated industry-level conversion cost estimates by scaling feedback from OEMs based on a combination of product offerings and U.S. market share estimates.

DOE adjusted the conversion cost estimates developed in support of the August 2022 NOPR to 2022$ for this analysis. DOE also estimated industry costs associated with appendix D2, as finalized in the October 2021 TP Final Rule. 86 FR 56608.

In general, DOE assumes all conversion-related investments occur between the year of publication of the final rule and the year by which manufacturers must comply with the new standard. The conversion cost figures used in the GRIM can be found in section V.B.2.a of this document. For additional information on the estimated capital and product conversion costs, *see* chapter 12 of the direct final rule TSD.

d. Manufacturer Markup Scenarios

MSPs include direct manufacturing production costs (*i.e.,* labor, materials, and overhead estimated in DOE's MPCs) and all non-production costs (*i.e.,* SG&A, R&D, and interest), along with profit. To calculate the MSPs in the GRIM, DOE applied manufacturer markups to the MPCs estimated in the engineering analysis for each product class and efficiency level. Modifying these markups in the standards case yields different sets of impacts on manufacturers. For the MIA, DOE modeled two standards-case scenarios to represent uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of amended energy conservation standards: (1) a preservation of gross margin percentage scenario and (2) a preservation-of-operating profit scenario. These scenarios lead to different manufacturer markup values that, when applied to the MPCs, result in varying revenue and cash flow impacts.

Under the preservation of gross margin percentage scenario, DOE applied a single uniform ''gross margin percentage'' across all efficiency levels, which assumes that manufacturers would be able to maintain the same amount of profit as a percentage of revenues at all efficiency levels within a product class. As manufacturer production costs increase with efficiency, this scenario implies that the per-unit dollar profit will increase. DOE assumed a gross margin percentage of approximately 21 percent for all product classes.[91] Manufacturers tend to believe it is optimistic to assume that they would be able to maintain the same gross margin percentage as their production costs increase, particularly for minimally efficient products. Therefore, this scenario represents a high bound to industry profitability under an amended energy conservation standard.

Under the preservation of operating profit scenario, DOE modeled a situation in which manufacturers are not able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE implemented this scenario in the GRIM by lowering the manufacturer markups at each TSL to yield approximately the same earnings before interest and taxes in the standards case as in the no-new-standards case in the year after the compliance date of the amended standards. The implicit assumption behind this scenario is that the industry can only maintain its operating profit in absolute dollars after the standard.

A comparison of industry financial impacts under the two manufacturer markup scenarios is presented in section V.B.2.a of this document.

3. Discussion of MIA Comments

For this direct final rule, DOE considered comments it had received regarding its manufacturer impact analysis presented in the August 2022 NOPR. The approach used for this direct final rule is largely the same as the approach DOE had used for the August 2022 NOPR analysis.

AHAM requested that DOE confirm it has fully included all costs that manufacturers would face in compliance to assure that the financial effects on manufacturers are not excessive. (AHAM, No. 46 at p. 11)

As discussed in section IV.J.2.c of this document, DOE primarily relied on manufacturer feedback to estimate the

[87] U.S. Department of Energy's Compliance Certification Database is available at *www.regulations.doe.gov/certification-data* (last accessed April 28, 2023).

[88] *Id.*

[89] ENERGY STAR Product Finder data set, available at *www.energystar.gov/productfinder* (last accessed April 28, 2023).

[90] California Energy Commission Modernized Appliance Efficiency Database System, available at *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx* (last accessed April 28, 2023).

[91] The gross margin percentage of 21 percent is based on a manufacturer markup of 1.26.

capital and product conversion costs that manufacturers would likely incur at the various analyzed efficiency levels. DOE did not receive additional feedback about its conversion cost estimates published in the August 2022 NOPR. Therefore, DOE did not significantly alter its conversion cost methodology in evaluating this direct final rule. DOE adjusted the conversion cost estimates developed in support of the NOPR to 2022$ for this analysis. Additionally, for this direct final rule, DOE updated its product conversion cost estimates to incorporate the estimated industry costs associated with rerating basic models in accordance with appendix D2. 86 FR 56608.

AHAM stated that if DOE is to consider amending energy conservation standards, it must incorporate into its analysis the challenges manufacturers are facing regarding the COVID–19 pandemic and increased tariffs. AHAM commented that DOE cannot simply rely on its previous analysis regarding component costs. (AHAM, No. 46 at pp. 13–14)

For this direct final rule, DOE updated its engineering analysis to incorporate up-to-date cost estimates. Increased costs associated with recent supply chain challenges stemming from the COVID–19 pandemic have been incorporated into the cost analysis by way of 5-year moving averages for materials and the most up-to-date costs for purchased parts.

AHAM stated that there will be an additional design cycle for either or both clothes washers and clothes dryers if the effective dates for the two products are out of sync. AHAM stated that the existing DOE analysis does not capture this situation, which creates a significant technical and financial burden on manufacturers. (AHAM, No. 46 at p. 11) AHAM stated its support for the ongoing Peer Review process regarding cumulative regulatory burden and stated that DOE should not discount the time and resources needed to evaluate and respond to all proposed test procedures and energy conservation standards for multiple products proposed over a short period. AHAM commented that when these rulemakings occur simultaneously, the cumulative burden increases dramatically. (AHAM, No. 46 at p. 13)

DOE notes that it is adopting the Recommended TSL in this direct final rule. The Joint Agreement included recommendations for other appliance standards rulemakings: residential clothes washers; consumer clothes dryers; consumer conventional cooking products; dishwashers; refrigerators, refrigerator-freezers, and freezers; and miscellaneous refrigeration products. The signatories indicate that the Joint Agreement for the six rulemakings should be considered as a joint recommendation of standards, to be adopted in its entirety. (Joint Agreement, No. 55 at p. 3) The Joint Agreement specifies a compliance date of March 1, 2028 for both residential clothes washers and consumer clothes dryers. Therefore, DOE did not adjust its conversion cost estimates to account for the time and investments associated with an additional design cycle as DOE assumed the compliance dates for residential clothes washers and consumer clothes dryers would align.

AHAM urged DOE to incorporate the financial results of the current cumulative regulatory burden analysis directly into the MIA and stated that this is achievable by adding the combined costs of complying with multiple regulations into the Product Conversion Costs in the GRIM model and including the costs to manufacturers of responding to and monitoring regulations. (AHAM, No. 46 at p. 11) AHAM requested that DOE explicitly recognize the industry effects of multiple regulations issued within a short period of time on the same product. AHAM stated that the MIA inherently assumes the regulation analyzed in the INPV analysis is a single event (investment) and that all other cash flows are unaffected by this regulation. In addition, AHAM stated that when there are multiple regulations on the same product within the 6-year lock-in period, the second regulation violates the recoupment assumption inherent in the first one, which is not considered by the GRIM model. AHAM stated that DOE could resolve this by conducting a consolidated analysis for multiple regulations starting from the time of the first regulation or by incorporating a value reduction factor in the first post-regulation year of the analysis that subtracts the value lost from the remaining years of the previous regulation. (*Id.* at pp. 11–12)

If DOE were to combine the conversion costs from multiple regulations, as requested, it would be appropriate to match the combined conversion costs with the combined revenues of the regulated products. DOE is concerned that combined results would make it more difficult to discern the direct impact of the amended standard on covered manufacturers, particularly for rulemakings where there is only partial overlap of manufacturers. Conversion costs would be spread over a larger revenue base and result in less severe INPV impacts when evaluated on a percent change basis. Furthermore, DOE is not aware of other Federal, product-specific regulations on consumer clothes dryers that would go into effect 3 years before or after the 2028 compliance date. DOE understands that if the effective dates of the consumer clothes dryer and residential clothes washer amended standards were misaligned, there could be additional development and marketing costs associated with aligning the design cycles of these products, as clothes dryers and clothes washers are typically designed and sold in pairs. However, DOE did not account for any additional development cost associated with this potential regulatory burden, as DOE modeled the recommended March 1, 2028 compliance date from the Joint Agreement for both rulemakings.

AHAM urged DOE to weigh in against regulatory misalignment with Natural Resources Canada (''NRCan'') through the United States-Canada Regulatory Cooperation Council work plan on energy efficiency and under the Memorandum of Understanding (''MOU'') on energy cooperation. AHAM also urged DOE to account for the burden of any misalignment in its analysis. According to AHAM, it is critical that amended standards are coordinated with NRCan, in both substance and timing, to maintain a consistent United States-Canadian market for home appliances. (AHAM, No. 46 at p. 13)

As part of the analysis underlying the energy conservation standards for consumer clothes dryers, DOE considers and reviews standards programs from other regions. As part of this effort, DOE considers regulatory actions undertaken by NRCan and notes that per a notice published on April 2, 2022 in the Canada Gazette, Part I,[92] NRCan is currently proceeding with pre-consultations to align the energy efficiency and testing standard for five home appliance categories including consumer clothes dryer with the outcomes of the current DOE regulatory efforts. Further detail regarding DOE's review of the NRCan regulatory actions and those in other regions are discussed in chapter 3 of the direct final rule TSD.

K. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential energy conservation standards on power sector and site (where applicable) combustion emissions of CO_2, NO_X, SO_2, and Hg. The second component estimates the

[92] The notice published in the Canada Gazette, Part I can be found at: *gazette.gc.ca/rp-pr/p1/2022/2022-04-02/html/notice-avis-eng.html#ne4.*

impacts of potential standards on emissions of two additional greenhouse gases, CH_4 and N_2O, as well as the reductions in emissions of other gases due to ''upstream'' activities in the fuel production chain. These upstream activities comprise extraction, processing, and transporting fuels to the site of combustion.

The analysis of electric power sector emissions of CO_2, NO_X, SO_2, and Hg uses emissions intended to represent the marginal impacts of the change in electricity consumption associated with amended or new standards. The methodology is based on results published for the *AEO,* including a set of side cases that implement a variety of efficiency-related policies. The methodology is described in appendix 13A in the direct final rule TSD. The analysis presented in this notice uses projections from *AEO2023.* Power sector emissions of CH_4 and N_2O from fuel combustion are estimated using Emission Factors for Greenhouse Gas Inventories published by the Environmental Protection Agency (EPA).[93]

The on-site operation of consumer clothes dryers involves combustion of fossil fuels and results in emissions of CO_2, NO_X, SO_2, CH_4, and N_2O where these products are used. Site emissions of these gases were estimated using Emission Factors for Greenhouse Gas Inventories and, for NO_X and SO_2, emissions intensity factors from an EPA publication.[94]

FFC upstream emissions, which include emissions from fuel combustion during extraction, processing, and transportation of fuels, and ''fugitive'' emissions (direct leakage to the atmosphere) of CH_4 and CO_2, are estimated based on the methodology described in chapter 15 of the direct final rule TSD.

The emissions intensity factors are expressed in terms of physical units per MWh or MMBtu of site energy savings. For power sector emissions, specific emissions intensity factors are calculated by sector and end use. Total emissions reductions are estimated using the energy savings calculated in the national impact analysis.

[93] Available at *www.epa.gov/sites/production/files/2021-04/documents/emission-factors_apr2021.pdf* (last accessed April 6, 2023).

[94] U.S. Environmental Protection Agency. External Combustion Sources. In *Compilation of Air Pollutant Emission Factors.* AP–42. Fifth Edition. Volume I: Stationary Point and Area Sources. Chapter 1. Available at *www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors#Proposed/* (last accessed May 26, 2023).

1. Air Quality Regulations Incorporated in DOE's Analysis

DOE's no-new-standards case for the electric power sector reflects the *AEO,* which incorporates the projected impacts of existing air quality regulations on emissions. *AEO2023* generally represents current legislation and environmental regulations, including recent government actions, that were in place at the time of preparation of *AEO2023,* including the emissions control programs discussed in the following paragraphs.[95]

SO_2 emissions from affected electric generating units (''EGUs'') are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (''DC''). (42 U.S.C. 7651 *et seq.*) SO_2 emissions from numerous States in the eastern half of the United States are also limited under the Cross-State Air Pollution Rule (''CSAPR''). 76 FR 48208 (Aug. 8, 2011). CSAPR requires these States to reduce certain emissions, including annual SO_2 emissions, and went into effect as of January 1, 2015.[96] *AEO2023* incorporates implementation of CSAPR, including the update to the CSAPR ozone season program emission budgets and target dates issued in 2016. 81 FR 74504 (Oct. 26, 2016). Compliance with CSAPR is flexible among EGUs and is enforced through the use of tradable emissions allowances. Under existing EPA regulations, for states subject to SO_2 emissions limits under CSAPR, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by another regulated EGU.

[95] For further information, see the Assumptions to *AEO2023* report that sets forth the major assumptions used to generate the projections in the Annual Energy Outlook. Available at *www.eia.gov/outlooks/aeo/assumptions/* (last accessed May 26, 2023).

[96] CSAPR requires states to address annual emissions of SO_2 and NO_X, precursors to the formation of fine particulate matter (''$PM_{2.5}$'') pollution, in order to address the interstate transport of pollution with respect to the 1997 and 2006 $PM_{2.5}$ National Ambient Air Quality Standards (''NAAQS''). CSAPR also requires certain states to address the ozone season (May–September) emissions of NO_X, a precursor to the formation of ozone pollution, in order to address the interstate transport of ozone pollution with respect to the 1997 ozone NAAQS. 76 FR 48208 (Aug. 8, 2011). EPA subsequently issued a supplemental rule that included an additional five states in the CSAPR ozone season program; 76 FR 80760 (Dec. 27, 2011) (Supplemental Rule), and EPA issued the CSAPR Update for the 2008 ozone NAAQS. 81 FR 74504 (Oct. 26, 2016).

However, beginning in 2016, SO_2 emissions began to fall as a result of the Mercury and Air Toxics Standards (''MATS'') for power plants. 77 FR 9304 (Feb. 16, 2012). The direct final rule establishes power plant emission standards for mercury, acid gases, and non-mercury metallic toxic pollutants. In order to continue operating, coal plants must have either flue gas desulfurization or dry sorbent injection systems installed. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions. Because of the emissions reductions under the MATS, it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by another regulated EGU. Therefore, energy conservation standards that decrease electricity generation will generally reduce SO_2 emissions. DOE estimated SO_2 emissions reduction using emissions factors based on *AEO2023.*

CSAPR also established limits on NO_X emissions for numerous States in the eastern half of the United States. Energy conservation standards would have little effect on NO_X emissions in those States covered by CSAPR emissions limits if excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions from other EGUs. In such case, NO_X emissions would remain near the limit even if electricity generation goes down. Depending on the configuration of the power sector in the different regions and the need for allowances, however, NO_X emissions might not remain at the limit in the case of lower electricity demand. That would mean that standards might reduce NO_X emissions in covered States. Despite this possibility, DOE has chosen to be conservative in its analysis and has maintained the assumption that standards will not reduce NO_X emissions in States covered by CSAPR. Standards would be expected to reduce NO_X emissions in the States not covered by CSAPR. DOE used *AEO2023* data to derive NO_X emissions factors for the group of States not covered by CSAPR.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would be expected to slightly reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on *AEO2023,* which incorporates the MATS.

EEI stated that the emissions estimates are significantly overstated

with the passage of the Inflation Reduction Act (''IRA''). EEI recommended that DOE update the analysis to account for the IRA and all the impacts in terms of the significantly increased use of renewable electricity as well as the increase in the number of utilities that have stated zero carbon electricity can be attained within the next 15 to 25 years. (EEI, No. 37 at pp. 54–55)

As previously stated, for the direct final rule DOE used the *AEO2023* Reference case, which includes the IRA, to represent the electric power sector over the coming decades. The *AEO2023* Reference case reflects EIA's view of the most likely uptake of IRA tax credits, and it assumes qualified technologies receive the base tax credit and some bonus credits. The IRA provisions, in combination with other policies and market forces, push wind and solar to 56 percent of electricity generation by 2050. DOE estimated emissions reductions from the adopted standards relative to this case.

L. Monetizing Emissions Impacts

As part of the development of this direct final rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are expected to result from each of the TSLs considered. In order to make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the projection period for each TSL. This section summarizes the basis for the values used for monetizing the emissions benefits and presents the values considered in this direct final rule.

To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

1. Monetization of Greenhouse Gas Emissions

DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the SC of each pollutant (*e.g.,* social costs of greenhouse gases ''SC–CO_2''). These estimates represent the monetary value '' of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services.

DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive orders, and DOE would reach the same conclusion presented in this rulemaking in the absence of the social cost of greenhouse gases. That is, the SC–CO_2, whether measured using the February 2021 interim estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases or by another means, did not affect the rule ultimately proposed by DOE.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions using SC–GHG values that were based on the interim values presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990,* published in February 2021 by the IWG. The SC–GHG is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, the SC–GHG includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHG therefore reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHG is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O, and CH_4 emissions. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG for this rule, which was developed using the interim estimates. DOE continues to evaluate recent developments in the scientific literature, including the updated SC–GHG estimates published by the EPA in December 2023 within their rulemaking on oil and natural gas sector sources.[97] For this rulemaking, DOE used these updated SC–GHG values to conduct a sensitivity analysis of the value of GHG emissions reductions associated with alternative standards for clothes dryers (see section IV.L.1.c of this document).

The SC–GHG estimates presented here were developed over many years, using peer-reviewed methodologies, a transparent process, the best science available at the time of that process, and input from the public. Specifically, in 2009, the IWG, which included DOE and other executive branch agencies and offices, was established to ensure that agencies were using the best available science and to promote consistency in the SC–CO_2 values used across agencies. The IWG published SC–CO_2 estimates in 2010 that were developed from an ensemble of three widely cited integrated assessment models (''IAMs'') that estimate global climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity—a measure of the globally averaged temperature response to increased atmospheric CO_2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016 the IWG published estimates of the social cost of methane (''SC–CH_4'') and nitrous oxide (''SC–N_2O'') using methodologies that are consistent with the methodology underlying the SC–CO_2 estimates. The modeling approach that extends the IWG SC–CO_2 methodology to non-CO_2 GHGs has undergone multiple stages of peer review. The SC–CH_4 and SC–N_2O estimates were developed by Marten et al.[98] and underwent a standard double-blind peer review process prior to journal publication. In 2015, as part of the response to public comments received following a 2013 solicitation for comments on the SC–CO_2 estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine review of the SC–CO_2 estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, *Valuing Climate Damages: Updating Estimation*

[97] Available at *www.epa.gov/system/files/documents/2023-12/eo12866_oil-and-gas-nsps-eg-climate-review-2060-av16-final-rule-20231130.pdf.*

[98] Marten, A.L., E.A. Kopits, C.W. Griffiths, S.C. Newbold, and A. Wolverton. Incremental CH_4 and N_2O mitigation benefits consistent with the U.S. Government's SC–CO_2 estimates. *Climate Policy.* 2015. 15(2): pp. 272–298.

of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the SC–CO_2 estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process (National Academies, 2017).[99] Shortly thereafter, in March 2017, President Trump issued Executive Order (''E.O.'') 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure SC–CO_2 estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4,[100] ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount rates'' (E.O. 13783, Section 5(c)). Benefit-cost analyses following E.O. 13783 used SC–GHG estimates that attempted to focus on the U.S.-specific share of climate change damages as estimated by the models and were calculated using two discount rates recommended by Circular A–4, 3 percent and 7 percent. All other methodological decisions and model versions used in SC–GHG calculations remained the same as those used by the IWG in 2010 and 2013, respectively.

On January 20, 2021, President Biden issued Executive Order 13990, which re-established the IWG and directed it to ensure that the U.S. Government's estimates of the social cost of carbon and other greenhouse gases reflect the best available science and the recommendations of the National Academies (2017). The IWG was tasked with first reviewing the SC–GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of E.O. 13990 that reflect the full impact of GHG emissions, including by taking global damages into account. The interim SC–GHG estimates published in February 2021 are used here to estimate the climate benefits for this rulemaking. E.O. 13990 instructs the IWG to undertake a fuller update of the SC–GHG estimates by January 2022 that takes into consideration the advice of the National Academies (2017) and other recent scientific literature. The February 2021 SC–GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways.

First, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to fully capture many climate impacts that affect the welfare of U.S. citizens and residents, and those impacts are better reflected by global measures of the SC–GHG. Examples of omitted effects from the E.O. 13783 estimates include direct effects on U.S. citizens, assets, and investments located abroad; supply chains, U.S. military assets and interests abroad, and tourism; and spillover pathways such as economic and political destabilization and global migration that can lead to adverse impacts on U.S. national security, public health, and humanitarian concerns. In addition, assessing the benefits of United States GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to United States citizens and residents by mitigating climate impacts that affect United States citizens and residents. A wide range of scientific and economic experts have emphasized the issue of reciprocity as support for considering global damages of GHG emissions. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. The only way to achieve an efficient allocation of resources for emissions reduction on a global basis—and so benefit the United States and its citizens—is for all countries to base their policies on global estimates of damages. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and, therefore, in this direct final rule DOE centers attention on a global measure of SC–GHG. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. A robust estimate of climate damages that accrue only to U.S. citizens and residents does not currently exist in the literature. As explained in the February 2021 TSD, existing estimates are both incomplete and an underestimate of total damages that accrue to the citizens and residents of the U.S. because they do not fully capture the regional interactions and spillovers previously discussed, nor do they include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature. As noted in the February 2021 SC–GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC–GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

Second, the IWG found that the use of the social rate of return on capital (7 percent under current OMB Circular A–4 guidance) to discount the future benefits of reducing GHG emissions inappropriately underestimates the impacts of climate change for the purposes of estimating the SC–GHG. Consistent with the findings of the National Academies (2017) and the economic literature, the IWG continued to conclude that the consumption rate of interest is the theoretically appropriate discount rate in an intergenerational context [101] and recommended that discount rate uncertainty and relevant aspects of intergenerational ethical considerations be accounted for in selecting future discount rates.

Furthermore, the damage estimates developed for use in the SC–GHG are estimated in consumption-equivalent terms, and so an application of OMB Circular A–4's guidance for regulatory analysis would then use the consumption discount rate to calculate the SC–GHG. DOE agrees with this assessment and will continue to follow

[99] National Academies of Sciences, Engineering, and Medicine. *Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide.* 2017. The National Academies Press: Washington, DC.

[100] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* Available at *www.whitehouse.gov/omb/information-for-agencies/circulars/* (last accessed April 20, 2023). DOE used the prior version of Circular A–4 (2003) as a result of the effective date of the new version.

[101] Interagency Working Group on Social Cost of Carbon, United States Government. Technical Support Document: Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. 2010. Available at *www.epa.gov/sites/default/files/2016-12/documents/scc_tsd_2010.pdf* (last accessed April 15, 2022); Interagency Working Group on Social Cost of Carbon, United States Government. Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. 2013. Available at *www.federalregister.gov/documents/2013/11/26/2013-28242/technical-support-document-technical-update-of-the-social-cost-of-carbon-for-regulatory-impact* (last accessed April 15, 2022); Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Technical Support Document: Technical Update on the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. August 2016. Available at *www.epa.gov/sites/default/files/2016-12/documents/sc_co2_tsd_august_2016.pdf* (last accessed Jan. 18, 2022); Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Addendum to Technical Support Document on Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866: Application of the Methodology to Estimate the Social Cost of Methane and the Social Cost of Nitrous Oxide. August 2016. Available at *www.epa.gov/sites/default/files/2016-12/documents/addendum_to_sc-ghg_tsd_august_2016.pdf* (last accessed Jan. 18, 2022).

developments in the literature pertaining to this issue. DOE also notes that while OMB Circular A–4, as published in 2003, recommends using 3-percent and 7-percent discount rates as ''default'' values, Circular A–4 also reminds agencies that ''different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.'' On discounting, Circular A–4 recognizes that ''special ethical considerations arise when comparing benefits and costs across generations,'' and Circular A–4 acknowledges that analyses may appropriately ''discount future costs and consumption benefits . . . at a lower rate than for intragenerational analysis.'' In the 2015 Response to Comments on the Social Cost of Carbon for Regulatory Impact Analysis, OMB, DOE, and the IWG members recognized that ''Circular A–4 is a living document'' and ''the use of 7 percent is not considered appropriate for intergenerational discounting. There is wide support for this view in the academic literature, and it is recognized in Circular A–4 itself.'' Thus, DOE concludes that a 7-percent discount rate is not appropriate to apply to value the social cost of greenhouse gases in the analysis presented in this document.

To calculate the present and annualized values of climate benefits, DOE uses the same discount rate as the rate used to discount the value of damages from future GHG emissions for internal consistency. That approach to discounting follows the same approach that the February 2021 TSD recommends ''to ensure internal consistency—*i.e.,* future damages from climate change using the SC–GHG at 2.5 percent should be discounted to the base year of the analysis using the same 2.5 percent rate.'' DOE has also consulted the National Academies' 2017 recommendations on how SC–GHG estimates can ''be combined in RIAs with other cost and benefits estimates that may use different discount rates.'' The National Academies reviewed several options, including ''presenting all discount rate combinations of other costs and benefits with [SC–GHG] estimates.''

As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with the above assessment and will continue to follow developments in the literature pertaining to this issue. While the IWG works to assess how best to incorporate the latest, peer-reviewed science to develop an updated set of SC–GHG estimates, it set the interim estimates to be the most recent estimates developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC–GHG TSD, the IWG has recommended that agencies revert to the same set of four values drawn from the SC–GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and were subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: an average value resulting from the model runs for each of three discount rates (2.5 percent, 3 percent, and 5 percent) plus a fourth value, selected as the 95th percentile of estimates based on a 3-percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC–GHG TSD, with which DOE agrees, this update reflects the immediate need to have an operational SC–GHG for use in regulatory benefit-cost analyses and other applications that was developed using a transparent process, peer-reviewed methodologies, and the science available at the time of that process. Those estimates were subject to public comment in dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

There are a number of limitations and uncertainties associated with the SC–GHG estimates. First, the current scientific and economic understanding of discounting approaches suggests discount rates appropriate for intergenerational analysis in the context of climate change are likely to be less than 3 percent, near 2 percent, or lower.[102] Second, the IAMs used to produce these interim estimates do not include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature, and the science underlying their ''damage functions''—*i.e.,* the core parts of the IAMs that map global mean temperature changes and other physical impacts of climate change into economic (both market and nonmarket) damages—lags behind the most recent research. For example, limitations include the incomplete treatment of catastrophic and non-catastrophic impacts in the integrated assessment models, their incomplete treatment of adaptation and technological change, the incomplete way in which interregional and intersectoral linkages are modeled, uncertainty in the extrapolation of damages to high temperatures, and inadequate representation of the relationship between the discount rate and uncertainty in economic growth over long time horizons. Likewise, the socioeconomic and emissions scenarios used as inputs to the models do not reflect new information from the last decade of scenario generation or the full range of projections. The modeling limitations do not all work in the same direction in terms of their influence on the SC–CO_2 estimates. However, as discussed in the February 2021 TSD, the IWG has recommended that, taken together, the limitations suggest that the interim SC–GHG estimates used in this direct final rule likely underestimate the damages from GHG emissions. DOE concurs with this assessment.

DOE's derivations of the SC–CO_2, SC–N_2O, and SC–CH_4 values used for this direct final rule are discussed in the following sections, and the results of DOE's analyses estimating the benefits of the reductions in emissions of these GHGs are presented in section V.B.6 of this document.

a. Social Cost of Carbon

The SC–CO_2 values used for this direct final rule were based on the values developed for the IWG's February 2021 TSD, which are shown in Table IV.22 in 5-year increments from 2020 to 2050. The set of annual values that DOE used, which was adapted from estimates published by EPA,[103] is presented in appendix 14A of the direct final rule TSD. These estimates are based on methods, assumptions, and parameters identical with the 2020–2050 estimates published by the IWG (which were based on EPA modeling) and include values for 2051 to 2070. DOE expects additional climate benefits to accrue for any longer-life consumer clothes dryers after 2070, but a lack of available SC–CO_2 estimates for

[102] Interagency Working Group on Social Cost of Greenhouse Gases (IWG), United States Government. Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990. February 2021. Available at *www.whitehouse.gov/briefing-room/blog/2021/02/26/a-return-to-science-evidence-based-estimates-of-the-benefits-of-reducing-climate-pollution/* (last accessed May 23, 2023).

[103] *See* EPA, Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis, Washington, DC, December 2021. Available at *nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1013ORN.pdf* (last accessed Feb. 21, 2023).

emissions years beyond 2070 prevents DOE from monetizing these potential benefits in this analysis.

For purposes of capturing the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of $SC–CO_2$ values, as recommended by the IWG.[104]

TABLE IV.22—ANNUAL $SC–CO_2$ VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per Metric Ton CO_2]

Year	Discount rate and statistic			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2020	14	51	76	152
2025	17	56	83	169
2030	19	62	89	187
2035	22	67	96	206
2040	25	73	103	225
2045	28	79	110	242
2050	32	85	116	260

DOE multiplied the CO_2 emissions reduction estimated for each year by the $SC–CO_2$ value for that year in each of the four cases. DOE adjusted the values to 2022$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the $SC–CO_2$ values in each case.

b. Social Cost of Methane and Nitrous Oxide

The $SC–CH_4$ and $SC–N_2O$ values used for this direct final rule were based on the values developed for the February 2021 TSD. Table IV.23 shows the updated sets of $SC–CH_4$ and $SC–N_2O$ estimates from the latest interagency update in 5-year increments from 2020 to 2050. The full set of annual values used is presented in appendix 14A of the direct final rule TSD. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of $SC–CH_4$ and $SC–N_2O$ values, as recommended by the IWG. DOE derived values after 2050 using the approach described above for the $SC–CO_2$.

TABLE IV.23.—ANNUAL $SC–CH_4$ AND $SC–N_2O$ VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per Metric Ton]

Year	$SC–CH_4$				$SC–N_2O$			
	Discount rate and statistic				Discount rate and statistic			
	5%	3%	2.5%	3%	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile	Average	Average	Average	95th percentile
2020	670	1500	2000	3900	5800	18000	27000	48000
2025	800	1700	2200	4500	6800	21000	30000	54000
2030	940	2000	2500	5200	7800	23000	33000	60000
2035	1100	2200	2800	6000	9000	25000	36000	67000
2040	1300	2500	3100	6700	10000	28000	39000	74000
2045	1500	2800	3500	7500	12000	30000	42000	81000
2050	1700	3100	3800	8200	13000	33000	45000	88000

DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the $SC–CH_4$ and $SC–N_2O$ estimates for that year in each of the cases. DOE adjusted the values to 2022$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the $SC–CH_4$ and $SC–N_2O$ estimates in each case.

c. Sensitivity Analysis Using Updated 2023 SC–GHG Estimates

In December 2023 EPA issued a new set of SC–GHG estimates (2023 SC–GHG) in connection with a final rulemaking under the Clean Air Act.[105] For this rulemaking, DOE used these updated 2023 SC–GHG values to conduct a sensitivity analysis of the value of GHG emissions reductions associated with alternative standards for consumer clothes dryers. This sensitivity analysis provides an expanded range of potential climate benefits associated with amended standards. The final year of EPA's new the 2023 SC–GHG estimates is 2080; therefore, DOE did not monetize the climate benefits of GHG emissions reductions occurring after 2080.

The overall climate benefits are larger using when using the higher, updated 2023 SC–GHG estimates, compared to the climate benefits using the older IWG SC–GHG estimates. However, DOE's conclusion that the standards are economically justified remains the same

[104] For example, the February 2021 TSD discusses how the understanding of discounting approaches suggests that discount rates appropriate for intergenerational analysis in the context of climate change may be lower than 3 percent.

[105] *See www.epa.gov/environmental-economics/scghg.*

regardless of which SC–GHG estimates are used.

The results of the sensitivity analysis are presented in appendix 14C of the direct final rule TSD.

2. Monetization of Other Emissions Impacts

For the direct final rule, DOE estimated the monetized value of NO_X and SO_2 emissions reductions from electricity generation using benefit-per-ton estimates for that sector from the EPA's Benefits Mapping and Analysis Program.[106] DOE used EPA's values for $PM_{2.5}$-related benefits associated with NO_X and SO_2 and for ozone-related benefits associated with NO_X for 2025 and 2030, and 2040, calculated with discount rates of 3 percent and 7 percent. DOE used linear interpolation to define values for the years not given in the 2025 to 2040 period; for years beyond 2040, the values are held constant. DOE combined the EPA benefit-per-ton estimates with regional information on electricity consumption and emissions to define weighted average national values for NO_X and SO_2 as a function of sector (*see* appendix 14B of the direct final rule TSD).

DOE also estimated the monetized value of NO_X and SO_2 emissions reductions from site use of natural gas in consumer clothes dryers using benefit-per-ton estimates from the EPA's Benefits Mapping and Analysis Program. Although none of the sectors covered by EPA refers specifically to residential and commercial buildings, the sector called ''area sources'' would be a reasonable proxy for residential and commercial buildings.[107] The EPA document provides high and low estimates for 2025 and 2030 at 3- and 7-percent discount rates.[108] DOE used the same linear interpolation and extrapolation as it did with the values for electricity generation.

DOE multiplied the site emissions reduction (in tons) in each year by the associated $/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate.

For this direct final rule, DOE considered comments it had received regarding its monetization emission impact analysis presented in the August 2022 NOPR. The approach used for this direct final rule is largely the same as the approach DOE had used for the August 2022 NOPR analysis.

In response to the August 2022 NOPR, AHAM disagreed with DOE's use of both the social cost of carbon (''SCC'') and other monetization of emissions reductions benefits in its analysis of the factors that EPCA requires DOE to balance in determining the appropriate standard, as these values are highly subjective and ever-changing. (AHAM, No. 46 at p. 14)

As stated in section III.E.1.f of this document, DOE maintains that environmental and public health benefits associated with more efficient use of energy, including those connected to global climate change, are important to take into account when considering the need for national energy conservation, which is one of the factors that EPCA requires DOE to evaluate in determining whether a potential energy conservation standard is economically justified. In addition, Executive Order 13563, which was reaffirmed on January 21, 2021, stated that each agency must, among other things, ''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).'' For these reasons, DOE includes monetized emissions reductions in its evaluation of potential standard levels. As previously stated, however, DOE would reach the same conclusion presented in this rulemaking in the absence of the SC–GHG. At the Recommended TSL, the average LCC savings for all product classes is positive. In addition, the FFC national energy savings are significant and the NPV of consumer benefits is positive using both a 3-percent and 7-percent discount rate. Even when measured at the more conservative discount rate of 7 percent, the NPV of consumer benefits is over 64 times higher than the maximum estimated manufacturers' loss in INPV.

M. Utility Impact Analysis

The utility impact analysis estimates the changes in installed electrical capacity and generation projected to result for each considered TSL. The analysis is based on published output from the NEMS associated with *AEO2023.* NEMS produces the *AEO* Reference case, as well as a number of side cases that estimate the economy-wide impacts of changes to energy supply and demand. For the current analysis, impacts are quantified by comparing the levels of electricity sector generation, installed capacity, fuel consumption, and emissions in the *AEO2023* Reference case and various side cases. Details of the methodology are provided in the appendices to chapters 13 and 15 of the direct final rule TSD.

The output of this analysis is a set of time-dependent coefficients that capture the change in electricity generation, primary fuel consumption, installed capacity and power sector emissions due to a unit reduction in demand for a given end use. These coefficients are multiplied by the stream of electricity savings calculated in the NIA to provide estimates of selected utility impacts of potential new or amended energy conservation standards.

The utility analysis also estimates the impact on gas utilities in terms of projected changes in natural gas deliveries to consumers for each TSL.

N. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a standard. Employment impacts from new or amended energy conservation standards include both direct and indirect impacts. Direct employment impacts are any changes in the number of employees of manufacturers of the products subject to standards, their suppliers, and related service firms. The MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more efficient appliances. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than in the manufacturing sector being regulated, caused by (1) reduced spending by consumers on energy, (2) reduced spending on new energy supply by the utility industry, (3) increased consumer spending on the products to which the new standards apply and other goods and services, and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Labor Department's Bureau of Labor Statistics (''BLS''). BLS regularly publishes its estimates of the number of

[106] Estimating the Benefit-per-Ton of Reducing Directly-Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. Available at *www.epa.gov/benmap/estimating-benefit-ton-reducing-pm25-precursors-21-sectors.*

[107] ''Area sources'' represents all emission sources for which states do not have exact (point) locations in their emissions inventories. Because exact locations would tend to be associated with larger sources, ''area sources'' would be fairly representative of small, dispersed sources like homes and businesses.

[108] ''Area sources'' are a category in the 2018 document from EPA but are not used in the 2021 document cited above. *See www.epa.gov/sites/default/files/2018-02/documents/sourceapportionmentbpttsd_2018.pdf.*

jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.[109] There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.,* the utility sector) to more labor-intensive sectors (*e.g.,* the retail and service sectors). Thus, the BLS data suggest that net national employment may increase due to shifts in economic activity resulting from energy conservation standards.

DOE estimated indirect national employment impacts for the standard levels considered in this direct final rule using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 4 (''ImSET'').[110] ImSET is a special-purpose version of the ''U.S. Benchmark National Input-Output'' (''I–O'') model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE notes that ImSET is not a general equilibrium forecasting model, and that the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may overestimate actual job impacts over the long run for this rule. Therefore, DOE used ImSET only to generate results for near-term timeframes (2027–2033) where these uncertainties are reduced.[111] For more details on the employment impact analysis, *see* chapter 16 of the direct final rule TSD.

O. Regulatory Impact Analysis

For any regulatory action that the Administrator of the Office of Information and Regulatory Affairs (''OIRA'') within OMB determines is a significant regulatory action under section 3(f)(1) of E.O. 12866, section 6(a)(3)(C) of E.O. 12866 requires Federal agencies to provide an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable non-regulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives. 58 FR 51735, 51741. As discussed further in section VI.A of this document, OIRA has determined that this final regulatory action constitutes a ''significant regulatory action'' within the scope of section 3(f)(1) of E.O. 12866, as amended by E.O. 14094. Accordingly, DOE conducted a regulatory impact analysis (''RIA'') for this direct final rule.

As part of the RIA, DOE identifies major alternatives to standards that represent feasible policy options to reduce the energy and water consumption of the covered product. DOE evaluates each alternative in terms of its ability to achieve significant energy and water savings at a reasonable cost, and compares the effectiveness of each alternative to the effectiveness of the finalized standard. DOE recognizes that voluntary or other non-regulatory efforts by manufacturers, utilities, and other interested parties can substantially affect energy and water efficiency or reduce energy and water consumption. DOE bases its assessment on the recorded impacts of any such initiatives to date, but also considers information presented by interested parties regarding the impacts current initiatives may have in the future. Further details regarding the RIA are provided in chapter 17 of the direct final rule TSD.

P. Other Comments

As discussed previously, DOE considered relevant comments, data, and information obtained during its own rulemaking process in determining whether the recommended standards from the Joint Agreement are in accordance with 42 U.S.C. 6295(o). And while some of those comments were directed at specific aspects of DOE's analysis of the Joint Agreement under 42 U.S.C. 6295(o), others were more generally applicable to DOE's energy conservation standards rulemaking program as a whole. The ensuing discussion focuses on these general comments concerning energy conservation standards issued under EPCA.

The National Academies of Sciences, Engineering, and Medicine (''NAS'') periodically appoint a committee to peer review the assumptions, models, and methodologies that DOE uses in setting energy conservation standards for covered products and equipment. The most recent such peer review was conducted in a series of meetings in 2020, and NAS issued the report [112] in 2021 detailing its findings and recommendations on how DOE can improve its analyses and align them with best practices for cost-benefit analysis.

AHAM recommended that DOE adopt the recommendations of the NAS report and incorporate the Regulatory Impact Analysis methodology of Office of Management and Budget (''OMB'') Circular A–4 and start with a more robust assessment of private market failures and alternatives to minimum standards that includes a robust identification and assessment of market failures by market segment. (AHAM, No. 46 at pp. 12–13)

AGA and APGA also commented that DOE should implement recommendations in the NAS report, specifically: appliance standards should be economically justified or based on significant failures of private markets or irrational consumer behavior (Recommendation 2–2); the Cost Analysis segment of the Engineering Analysis should be expanded to include ranges of costs, patterns of consumption, diversity factors, energy peak demand, and variance regarding environmental factors (Recommendation 3–5); DOE should put greater weight on ex post and market-based evidence of markups to project a more realistic range of effects of a standard on prices (Recommendation 4–1); DOE should place greater emphasis on providing an argument for

[109] *See* U.S. Department of Commerce—Bureau of Economic Analysis. *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (''RIMS II'').* 1997. U.S. Government Printing Office: Washington, DC. Available at *www.osti.gov/biblio/7281092* (last accessed July 1, 2021).

[110] Livingston, O.V., S.R. Bender, M.J. Scott, and R.W. Schultz. *ImSET 4.0: Impact of Sector Energy Technologies Model Description and User's Guide.* 2015. Pacific Northwest National Laboratory: Richland, WA. PNNL–24563. Available at *www.pnnl.gov/main/publications/external/technical_reports/PNNL-24563.pdf* (last accessed April 26, 2023).

[111] The near-term timeframes for the Recommended TSL are 2028–2034.

[112] Review of Methods Used by the U.S. Department of Energy in Setting Appliance and Equipment Standards (2021), available at *nap.nationalacademies.org/25992.*

the plausibility and magnitude of any market failure related to the energy efficiency gap in its analyses (Recommendation 4–13); and DOE should give greater attention to a broader set of potential market failures on the supply side, including how standards might reduce the number of competing firms, and also how standards might impact price discrimination, technological diffusion, and collusion (Recommendation 4–14). (APGA *et al.,* No. 47 at pp. 2–3)

The rulemaking process for standards of covered products and equipment are outlined at appendix A to subpart C of 10 CFR part 430, and DOE periodically examines and revises these provisions in separate rulemaking proceedings. The recommendations in the NAS report cited by commenters on the August 2022 NOPR, which pertain to the processes by which DOE analyzes energy conservation standards, will be considered in a separate rulemaking considering all product categories.

V. Analytical Results and Conclusions

The following section addresses the results from DOE's analyses with respect to the considered energy conservation standards for consumer clothes dryers. It addresses the TSLs examined by DOE, the projected impacts of each of these levels if adopted as energy conservation standards for consumer clothes dryers, and the standards levels that DOE is adopting in this direct final rule. Additional details regarding DOE's analyses are contained in the direct final rule TSD supporting this document.

A. Trial Standard Levels

In general, DOE typically evaluates potential amended standards for products and equipment by grouping individual efficiency levels for each class into TSLs. Use of TSLs allows DOE to identify and consider manufacturer cost interactions between the product classes, to the extent that there are such interactions, and market cross elasticity from consumer purchasing decisions that may change when different standard levels are set.

In the analysis conducted for this direct final rule, DOE analyzed the benefits and burdens of six TSLs for consumer clothes dryers. DOE developed TSLs that combine efficiency levels for each analyzed product class/category using similar technologies and/or efficiencies and having roughly comparable equipment availability. DOE presents the results for the TSLs in this document, while the results for all efficiency levels that DOE analyzed are in the direct final rule TSD. DOE presents the results for the TSLs in this document, while the results for all efficiency levels that DOE analyzed are in the direct final rule TSD.

Table V.1 presents the TSLs and the corresponding efficiency levels that DOE has identified for potential amended energy conservation standards for consumer clothes dryers. For the vented gas compact product class, all TSLs represent the baseline efficiency level because there are no higher efficiency levels, and this level corresponds to the efficiency level for vented gas compact clothes dryers in the Recommended TSL in the Joint Agreement. For all remaining product classes, the TSLs are defined as follows. TSL 6 represents the maximum technologically feasible (''max-tech'') energy efficiency. TSL 5 represents the maximum national energy savings with maximum positive NPV. TSL 4 represents the maximum national energy savings with simple PBP less than 4 years. TSL 3—which corresponds to the Recommended TSL in the Joint Agreement—represents the intermediate efficiency level between TSL 2 and TSL 4. TSL 2 corresponds to the efficiency level with high-speed spin for ventless electric combination washer-dryer and automatic termination control system for all other product classes. TSL 1 corresponds to the efficiency level with electronic controls.

TABLE V.1—TRIAL STANDARD LEVELS FOR CONSUMER CLOTHES DRYERS

Product class	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Efficiency level and representative CEF_{D2} (*lb/kWh*)						
Electric, Standard	1 (2.68)	3 (3.27)	4 (3.93)	5 (4.21)	7 (7.39)	7 (7.39)
Electric, Compact (120V)	1 (3.15)	3 (4.28)	4 (4.33)	4 (4.33)	4 (4.33)	6 (6.37)
Vented Electric, Compact (240V)	1 (2.44)	3 (3.30)	4 (3.57)	4 (3.57)	5 (3.82)	6 (3.91)
Vented Gas, Standard	1 (2.44)	2 (3.00)	3 (3.48)	3 (3.48)	4 (3.83)	4 (3.83)
Vented Gas, Compact	Baseline (2.02)	Baseline (2.02)	Baseline (2.02)	Baseline (2.02)	Baseline (2.02)	Baseline (2.02)
Ventless Electric, Compact (240V).	Baseline (2.03)	1 (2.68)	1 (2.68)	1 (2.68)	1 (2.68)	2 (6.80)
Ventless Electric, Combination Washer-Dryer.	Baseline (2.27)	1 (2.33)	1 (2.33)	1 (2.33)	1 (2.33)	2 (4.01)

DOE constructed the TSLs for this direct final rule to include efficiency levels (''ELs'') representative of ELs with similar characteristics (*i.e.,* using similar technologies and/or efficiencies, and having roughly comparable equipment availability). The use of representative ELs provided for greater distinction between the TSLs. While representative ELs were included in the TSLs, DOE considered all ELs as part of its analysis but did not include all ELs in the TSLs.[113]

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

DOE analyzed the economic impacts on consumers of consumer clothes dryers by looking at the effects that potential amended standards at each TSL would have on the LCC and PBP. DOE also examined the impacts of potential standards on selected consumer subgroups. These analyses are discussed in the following sections.

a. Life-Cycle Cost and Payback Period

In general, higher efficiency products affect consumers in two ways: (1) purchase price increases and (2) annual operating costs decrease. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.,* product price plus installation costs) and operating costs (*i.e.,* annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The LCC calculation also uses product lifetime and a discount rate. Chapter 8 of the

[113] Efficiency levels that were analyzed for this final rule are discussed in section IV.C.1 of this document. Results by efficiency level are presented in the final rule TSD chapters 8 and 10.

direct final rule TSD provides detailed information on the LCC and PBP analyses.

Table V.2 through Table V.13 show the LCC and PBP results for the TSLs considered for each product class. In the first of each pair of tables, the simple payback is measured relative to the baseline product. In the second table, the impacts are measured relative to the efficiency distribution in the in the no-new-standards case in the compliance year (*see* section IV.F.8 of this document). Because some consumers purchase products with higher efficiency in the no-new-standards case, the average savings are less than the difference between the average LCC of the baseline product and the average LCC at each TSL. The savings refer only to consumers who are affected by a standard at a given TSL. Those who already purchase a product with efficiency at or above a given TSL are not affected. Consumers for whom the LCC increases at a given TSL experience a net cost.

TABLE V.2—AVERAGE LCC AND PBP RESULTS FOR ELECTRIC STANDARD CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Average costs (2022$)				Simple payback period (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
.....	2.20	Baseline	$656	$111	$1,251	$1,907	.....	14
1	2.68	1	666	94	1,082	1,748	0.5	14
2	3.27	3	672	79	922	1,594	0.5	14
3*	3.93	4	678	67	802	1,480	0.6	14
4	4.21	5	756	64	759	1,515	2.1	14
5, 6	7.39	7	1,055	42	514	1,569	5.8	14

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.3—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR ELECTRIC STANDARD CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-cycle cost savings	
			Average LCC savings* (2022$)	Percentage of consumers that experience net cost (%)
1	2.68	1	$150	1.2
2	3.27	3	170	0.9
3**	3.93	4	252	0.9
4	4.21	5	100	48.0
5, 6	7.39	7	41	63.1

* The savings represent the average LCC for affected consumers.

** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.4—AVERAGE LCC AND PBP RESULTS FOR ELECTRIC COMPACT (120V) CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Average costs (2022$)				Simple payback period (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
.....	2.36	Baseline	$683	$40	$325	$1,136	.....	14
1	3.15	1	695	32	257	1,082	1.5	14
2	4.28	3	704	25	199	1,017	1.5	14
3*	4.33	4	712	25	198	1,023	2.2	14
4, 5	4.33	4	715	25	198	1,026	2.2	14
6	6.37	6	1,057	19	146	1,301	18.1	14

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.5—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR ELECTRIC COMPACT (120V) CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-cycle cost savings	
			Average LCC savings* (2022$)	Percentage of consumers that experience net cost (%)
1	3.15	1	$53	4.8
2	4.28	3	83	5.1
**3	4.33	4	66	21.4
4, 5	4.33	4	66	21.7

TABLE V.5—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR ELECTRIC COMPACT (120V) CONSUMER CLOTHES DRYERS—Continued

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-cycle cost savings	
			Average LCC savings * (2022$)	Percentage of consumers that experience net cost (%)
6	6.37	6	(209)	90.9

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.6—AVERAGE LCC AND PBP RESULTS FOR ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Average costs (2022$)				Simple payback period (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
.....	2.00	Baseline	$685	$47	$541	$1,226	.....	14
1	2.44	1	698	41	490	1,187	2.1	14
2	3.30	3	707	32	394	1,101	1.5	14
3 *	3.57	4	714	30	375	1,090	2.0	14
4	3.57	4	718	30	374	1,092	2.0	14
5	3.82	5	802	29	357	1,160	6.6	14
6	3.91	6	1,059	29	352	1,412	20.4	14

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.
* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.7—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR VENTED ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-Cycle cost savings	
			Average LCC savings * (2022$)	Percentage of consumers that experience net cost (%)
1	2.44	1	$38	5.7
2	3.30	3	89	4.6
3 **	3.57	4	90	12.4
4	3.57	4	90	12.6
5	3.82	5	22	60.7
6	3.91	6	(230)	92.8

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.8—AVERAGE LCC AND PBP RESULTS FOR VENTED GAS STANDARD CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Average costs (2022$)				Simple payback period (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
.....	2.00	Baseline	$794	$56	$668	$1,461	.....	14
1	2.44	1	810	50	607	1,417	2.5	14
2	3.00	2	813	41	511	1,324	1.3	14
3 *	3.48	3	825	36	465	1,291	1.9	14
4	3.48	3	830	37	464	1,293	1.9	14
5, 6	3.83	4	904	34	429	1,333	5.0	14

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.
* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.9—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR VENTED GAS STANDARD CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-cycle cost savings	
			Average LCC savings * (2022$)	Percentage of consumers that experience net cost (%)
1	2.44	1	$48	2.7%
2	3.00	2	112	1.7
3 **	3.48	3	102	7.1
4	3.48	3	102	7.0
5, 6	3.83	4	13	68.7

* The savings represent the average LCC for affected consumers.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.10—AVERAGE LCC AND PBP RESULTS FOR VENTLESS ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Average costs (2022$)				Simple payback period (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
	2.03	Baseline	$1,020	$41	$475	$1,495		14
1	2.03	Baseline	1,020	41	475	1,495		14
2, 4, 5	2.68	1	1,024	31	368	1,392	0.4	14
3 *	2.68	1	1,018	30	370	1,387	0.4	14
6	6.80	2	1,346	12	167	1,513	11.4	14

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.
* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.11—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR VENTLESS ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-cycle cost savings	
			Average LCC savings * (2022$)	Percentage of consumers that experience net cost (%)
1	2.03	Baseline		
2, 4, 5	2.68	1	99	0.0
3 **	2.68	1	99	0.0
6	6.80	2	(102)	58.6

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.12—AVERAGE LCC AND PBP RESULTS FOR VENTLESS ELECTRIC COMBINATION WASHER-DRYER CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Average costs (2022$)				Simple payback period (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
1	2.27	Baseline	$1,335	$37	$445	$1,780		14
2, 4, 5	2.33	1	1,335	36	435	1,769	0.0	14
3 *	2.33	1	1,327	36	436	1,763	0.0	14
6	4.01	2	2,031	22	275	2,305	46.3	14

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.
* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.13—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR VENTLESS ELECTRIC COMBINATION WASHER-DRYER CONSUMER CLOTHES DRYERS

TSL	CEF_{D2} (lb/kWh)	Efficiency level	Life-cycle cost savings	
			Average LCC savings* (2022$)	Percentage of consumers that experience net cost (%)
1	2.27	Baseline	.....	.....
2, 4, 5	2.33	1	$10	0.0
3**	2.33	1	11	0.0
6	4.01	2	(531)	95.0

*The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

b. Consumer Subgroup Analysis

In the consumer subgroup analysis, DOE estimated the impact of the considered TSLs on low-income households and senior-only households. Table V.14 through Table V.25 compare the average LCC savings, PBP, percent of consumers negatively impacted, and percent of consumers positively impacted at each EL for the consumer subgroups, along with corresponding values for the entire residential consumer sample for product classes with a sufficient sample size. In most cases, the average LCC savings and PBP for low-income households and senior-only households at the considered ELs are not substantially different from the average for all households. Chapter 11 of the direct final rule TSD presents the complete LCC and PBP results for the subgroups.

TABLE V.14—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: ELECTRIC STANDARD CONSUMER CLOTHES DRYERS

EL	TSL	Average life-cycle cost savings* (2022$)			Simple payback period (years)		
		Low-income households	Senior-only households	All households	Low-income households	Senior-only households	All households
1	1	$148	$110	$150	0.3	0.7	0.5
3	2	166	128	170	0.3	0.6	0.5
4	**3	245	190	252	0.3	0.8	0.6
5	4	127	58	100	1.1	2.8	2.1
7	5, 6	180	(56)	41	3.2	7.6	5.8

*The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.15—COMPARISON OF PERCENTAGES OF IMPACTED CONSUMERS* FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: ELECTRIC STANDARD CONSUMER CLOTHES DRYERS

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
1	1	1.3	1.4	1.2
3	2	1.0	1.1	0.9
4	**3	0.8	1.1	0.9
5	4	26.6	53.6	48.0
7	5, 6	34.9	71.6	63.1

*Percentage of impacted consumers indicates households with net cost.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.16—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: ELECTRIC COMPACT (120V) CONSUMER CLOTHES DRYERS

EL	TSL	Average life-cycle cost savings* (2022$)			Simple payback period (years)		
		Low-income households	Senior-only households	All households	Low-income households	Senior-only households	All households
1	1	$67	$34	$53	0.7	2.1	1.5
3	2	96	61	83	0.7	1.9	1.5
4	**3	84	46	66	1.0	2.9	2.2
4	4, 5	83	46	66	1.0	2.9	2.2
6	6	(23)	(243)	(209)	8.5	23.4	18.1

*The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.17—COMPARISON OF PERCENTAGES OF IMPACTED CONSUMERS * FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: ELECTRIC COMPACT (120V) CONSUMER CLOTHES DRYERS

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
1	1	4.0	5.0	4.8
3	2	3.8	5.6	5.1
4	** 3	12.2	24.8	21.4
4	4, 5	12.2	25.0	21.7
6	6	43.9	94.9	90.9

* Percentage of impacted consumers indicates households with net cost.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.18—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTED ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

EL	TSL	Average life-cycle cost savings * (2022$)			Simple payback period (years)		
		Low-income households	Senior-only households	All households	Low-income households	Senior-only households	All households
1	1	$51	$22	$38	1.0	2.8	2.1
3	2	102	66	89	0.7	2.0	1.5
4	** 3	109	65	90	1.0	2.6	2.0
4	4	109	64	90	1.0	2.6	2.0
5	5	83	(7)	22	3.1	8.5	6.6
6	6	(45)	(260)	(230)	9.6	26.5	20.4

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.19—COMPARISON OF PERCENT OF IMPACTED CONSUMERS * FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTED ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
1	1	4.5	6.0	5.7
3	2	3.7	5.0	4.6
4	** 3	7.4	15.1	12.4
4	4	7.5	15.3	12.6
5	5	30.0	68.5	60.7
6	6	44.9	96.1	92.8

* Percent of impacted consumers indicates households with net cost.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.20—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTED GAS STANDARD CONSUMER CLOTHES DRYERS

EL	TSL	Average life-cycle cost savings * (2022$)			Simple payback period (years)		
		Low-income households	Senior-only households	All households	Low-income households	Senior-only households	All households
1	1	$57	$33	$48	1.3	3.3	2.5
2	2	117	91	112	0.7	1.6	1.3
3	** 3	113	81	102	1.0	2.4	1.9
3	4	113	81	102	1.0	2.4	1.9
4	5, 6	54	(5)	13	2.7	6.3	5.0

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.21—COMPARISON OF PERCENTAGES OF IMPACTED CONSUMERS * FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTED GAS STANDARD CONSUMER CLOTHES DRYERS

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
1	1	2.4	3.0	2.7
2	2	1.6	1.7	1.7
3	** 3	4.8	8.9	7.1
3	3, 4	4.8	8.8	7.0

TABLE V.21—COMPARISON OF PERCENTAGES OF IMPACTED CONSUMERS * FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTED GAS STANDARD CONSUMER CLOTHES DRYERS—Continued

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
4	5, 6	35.9	74.5	68.7

* Percentage of impacted consumers indicates households with net cost.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.22—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTLESS ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

EL	TSL	Average life-cycle cost savings * (2022$)			Simple payback period (years)		
		Low-income households	Senior-only households	All households	Low-income households	Senior-only households	All households
0	1	.....	.....	.....	.....	.....	.....
1	2, 4, 5	$108	$80	$99	0.2	0.5	0.4
1	**3	108	80	99	0.2	0.5	0.4
2	6	64	(147)	(102)	5.4	14.5	11.4

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.23—COMPARISON OF PERCENT OF IMPACTED CONSUMERS * FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTLESS ELECTRIC COMPACT (240V) CONSUMER CLOTHES DRYERS

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
0	1	.....	.....	.....
1	2, 4, 5	0.0	0.0	0.0
2	**3	0.0	0.0	0.0
2	6	27.8	63.4	58.6

* Percentage of impacted consumers indicates households with net cost.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.24—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTLESS ELECTRIC COMBINATION WASHER-DRYER CONSUMER CLOTHES DRYERS

EL	TSL	Average life-cycle cost savings * (2022$)			Simple payback period (years)		
		Low-income households	Senior-only households	All households	Low-income households	Senior-only households	All households
0	1	.....	.....	.....	.....	.....	.....
1	2, 4, 5	$11	$8	$10	0.0	0.0	0.0
1	**3	11	8	11	0.0	0.0	0.0
2	6	(186)	(565)	(531)	22.0	58.6	46.3

* The savings represent the average LCC for affected consumers. Negative values are denoted in parentheses.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

TABLE V.25—COMPARISON OF PERCENTAGES OF IMPACTED CONSUMERS * FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS: VENTLESS ELECTRIC COMBINATION WASHER-DRYER CONSUMER CLOTHES DRYERS

EL	TSL	Low-income households (%)	Senior-only households (%)	All households (%)
0	1	.....	.....	.....
1	2, 4, 5	0.0	0.0	0.0
1	**3	0.0	0.0	0.0
2	6	44.8	96.2	95.0

* Percentage of impacted consumers indicates households with net cost.
** All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

c. Rebuttable Presumption Payback

As discussed in section II.A of this document, EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. In calculating a rebuttable presumption payback period for each of the considered TSLs, DOE used discrete values, and, as required by EPCA, based the energy use calculation on the DOE test procedures for consumer clothes dryers. In contrast, the PBPs presented in section V.B.1.a of this document were calculated using distributions that reflect the range of energy use in the field.

Table V.26 presents the rebuttable presumption payback periods for the considered TSLs for consumer clothes dryers. While DOE examined the rebuttable presumption criterion, it considered whether the standard levels considered for this rule are economically justified through a more detailed analysis of the economic impacts of those levels, pursuant to 42 U.S.C. 6295(o)(2)(B)(i), that considers the full range of impacts to the consumer, manufacturer, Nation, and environment. The results of that analysis serve as the basis for DOE to definitively evaluate the economic justification for a potential standard level, thereby supporting or rebutting the results of any preliminary determination of economic justification.

TABLE V.26—REBUTTABLE PRESUMPTION PAYBACK PERIODS

Product class	Trial standard level					
	1	2	3*	4	5	6
	(years)					
Electric, Standard	0.4	0.3	0.4	1.5	4.1	4.1
Electric, Compact (120 V)	1.0	1.0	1.6	1.6	1.6	13.0
Vented Electric, Compact (240 V)	3.2	1.0	1.4	1.4	4.6	14.2
Vented Gas, Standard	3.1	2.0	2.9	2.8	7.8	7.8
Ventless Electric, Compact (240 V)	.....	0.3	0.3	0.3	0.3	8.8
Ventless Electric, Combination Washer-Dryer	.....	0.0	0.0	0.0	0.0	33.8

* All TSLs except TSL 3 (the Recommended TSL) have a compliance year of 2027. TSL 3 has a compliance year of 2028.

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of amended energy conservation standards on manufacturers of consumer clothes dryers. The next section describes the expected impacts on manufacturers at each considered TSL. Chapter 12 of the direct final rule TSD explains the analysis in further detail.

a. Industry Cash Flow Analysis Results

In this section, DOE provides GRIM results from the analysis, which examines changes in the industry that would result from a standard. The following tables summarize the estimated financial impacts (represented by changes in INPV) of potential amended energy conservation standards on manufacturers of consumer clothes dryers, as well as the conversion costs that DOE estimates manufacturers of consumer clothes dryers would incur at each TSL.

The impacts of potential amended energy conservation standards were analyzed under two scenarios: (1) the preservation of gross margin percentage; and (2) the preservation of operating profit as discussed in section IV.J.2.d of this document. In the preservation-of-gross-margin-percentage scenario, DOE applied a gross margin percentage of 21 percent for all product classes and all efficiency levels in the standards case.[114] This scenario assumes that a manufacturer's per-unit dollar profit would increase as MPCs increase in the standards cases. DOE models this scenario as an upper bound to industry profitability under an energy conservation standard.

In the preservation-of-operating-profit scenario, manufacturers do not earn additional operating profit when compared to the no-new-standards case scenario. While manufacturers make the necessary upfront investments required to produce compliant products, per-unit operating profit does not change in absolute dollars. DOE models this scenario as the lower bound to industry profitability under an energy conservation standard.

Each of the modeled scenarios results in a unique set of cash flows and corresponding INPV for each TSL. INPV is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (30 years from the analyzed compliance year).[115] The ''change in INPV'' results refer to the difference in industry value between the no-new-standards case and standards case at each TSL. To provide perspective on the short-run cash-flow impact, DOE includes a comparison of free cash flow between the no-new-standards case and the standards case at each TSL in the year before amended standards would take effect. This figure provides an understanding of the magnitude of the required conversion costs relative to the cash flow generated by the industry in the no-new-standards case.

Conversion costs are one-time investments for manufacturers to bring their manufacturing facilities and product designs into compliance with potential amended standards. As described in section IV.J.2.c of this document, conversion cost investments occur between the year of publication of the direct final rule and the year by which manufacturers must comply with the new standard. The conversion costs can have a significant impact on short-term cash flow within the industry and generally result in lower free cash flow in the period between publication of the direct final rule and the compliance date of potential amended standards. Conversion costs are independent of the manufacturer markup scenarios and are not presented as a range in this analysis.

[114] The gross margin percentage of 21 percent is based on a manufacturer markup of 1.26.

[115] The analysis period ranges from 2024–2056 for the no-new-standards case and all TSLs, except for TSL 3 (the Recommended TSL). The analysis period for TSL 3 ranges from 2024–2057 due to the 2028 compliance year.

TABLE V.27—MANUFACTURER IMPACT ANALYSIS RESULTS FOR CONSUMER CLOTHES DRYERS

	Units	No-new-standards case	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
INPV	*2022$ millions.*	2,115.4	2,080.3 to 2,084.3.	2,061.1 to 2,069.5.	1,971.2 to 1,995.8.	1,501.9 to 1,724.8.	679.9 to 1,800.8.	604.3 to 1,753.5
Change in INPV *	%		(1.7) to (1.5)	(2.6) to (2.2)	(6.8) to (5.7)	(29.0) to (18.5)	(67.9) to (14.9).	(71.4) to (17.1)
Free Cash Flow (2026) **	*2022$ millions.*	*** 136.7	119.2	109.7	61.2	(153.7)	(496.0)	(531.4)
Change in Free Cash Flow (2026) **.	%		(12.8)	(19.8)	(55.2)	(212.5)	(462.9)	(488.8)
Product Conversion Costs	*2022$ millions.*		27.3	37.6	51.7	87.7	122.6	128.2
Capital Conversion Costs	*2022$ millions.*		18.6	31.9	128.9	579.7	1,314.3	1,388.8
Total Conversion Costs	*2022$ millions.*		45.8	69.5	180.7	667.5	1,436.9	1,516.9

* Parentheses denote negative values.
** TSL 3 (the Recommended TSL) represents the change in free cash flow in 2027, a year before the 2028 compliance date.
*** In 2027, the no-new-standards free cash flow is $136.6 million.

The cash flow results discussion below refers to product classes as defined in Table IV.1 in section IV.A.1 of this document. It also refers to the efficiency levels and associated design options designated in Table IV.5 through Table IV.10 in section IV.C.1.b of this document.

At TSL 1, the standard reflects efficiency levels with electronic controls for all product classes. The change in INPV is expected to range from −1.7 to −1.5 percent. At this level, free cash flow is estimated to decrease by 12.8 percent compared to the no-new-standards case value of $136.7 million in the year 2026, the year before the 2027 standards year. DOE's shipments analysis estimates approximately 85 percent of current shipments meet this level.[116]

The design options DOE analyzed include implementing electronic controls. For electric standard, electric compact (120V), vented electric compact (240V), and vented gas standard, TSL 1 corresponds to EL 1. For ventless electric compact (240V) and ventless electric combination washer-dryer, TSL 1 corresponds to the baseline CEF_{D2}. Capital conversion costs may be necessary for additional tooling for timers and electronics. Product conversion costs may be necessary for developing, sourcing, and testing electronics (*e.g.,* safety, performance, and durability tests). DOE does not expect industry to incur re-flooring costs at this level since the necessary enhancements could be done ''behind the hinge,'' incorporating the design changes in a manner that does not impact product appearance. DOE does not expect industry to incur conversion costs related to the ventless electric compact (240V) or ventless electric combination washer-dryer as the efficiency levels would remain at baseline. DOE estimates capital conversion costs of $18.6 million and product conversion costs of $27.3 million. Conversion costs total $45.8 million.

At TSL 1, the shipment-weighted average MPC for all consumer clothes dryers is expected to increase by 0.3 percent relative to the no-new-standards case shipment-weighted average MPC for all consumer clothes dryers in 2027. Given this relatively small increase in production costs, DOE does not project a notable drop in shipments in the year the standard takes effect. In the preservation-of-gross-margin-percentage scenario, the slight increase in cash flow from the higher MSP is outweighed by the $45.8 million in conversion costs, causing a slightly negative change in INPV at TSL 1 under this scenario. Under the preservation-of-operating-profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case, but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2028, the year after the analyzed 2027 compliance year. This reduction in the manufacturer markup and the $45.8 million in conversion costs incurred by manufacturers cause a slightly negative change in INPV at TSL 1 under the preservation-of-operating-profit scenario.

At TSL 2, the standard reflects efficiency levels with more advanced automatic termination controls for electric standard, electric compact (120V), vented electric compact (240V), vented gas standard, and ventless electric compact (240V), and high-speed spin for ventless electric combination washer-dryer. The change in INPV is expected to range from −2.6 to −2.2 percent. At this level, free cash flow is estimated to decrease 19.8 percent compared to the no-new-standards case value of $136.7 million in the year 2026, the year before the 2027 standards year. DOE's shipments analysis estimates approximately 58 percent of current shipments meet this level.

The design options for electric standard, electric compact (120V), vented electric compact (240V), vented gas standard, and ventless electric compact (240V) include implementing electronic controls, optimized heating systems, and more advanced automatic termination controls. For ventless electric combination washer-dryer, the design option analyzed includes high-speed spin cycles. For the electric standard, electric compact (120V), and vented electric compact (240V), TSL 2 corresponds to EL 3. For vented gas standard, TSL 2 corresponds to EL 2. For ventless electric compact (240V) and ventless electric combination washer-dryer, TSL 2 corresponds to EL 1. Capital conversion costs may be necessary for incremental updates in tooling. Product conversion costs may be necessary for software optimization, prototyping, and testing. DOE expects industry to incur some re-flooring costs as manufacturers redesign product lines to meet the efficiency levels required by TSL 2. DOE estimates capital conversion costs of $31.9 million and product conversion costs of $37.6 million. Conversion costs total $69.5 million.

At TSL 2, the shipment-weighted average MPC for all consumer clothes dryers is expected to increase by 0.6 percent relative to the no-new-standards case shipment-weighted average MPC for all consumer clothes dryers in 2027. Given the relatively small increase in production costs, DOE does not project a notable drop in shipments in the year

[116] Current shipments calculations relied on shipments in 2024 (the reference year).

the standard takes effect. In the preservation-of-gross-margin-percentage scenario, the slight increase cash flow from the higher MSP is outweighed by the $69.5 million in conversion costs, causing a slightly negative change in INPV at TSL 2 under this scenario. Under the preservation-of-operating-profit scenario, the manufacturer markup decreases in 2028, the year after the analyzed 2027 compliance year. This reduction in the manufacturer markup and the $69.5 million in conversion costs incurred by manufacturers cause a negative change in INPV at TSL 2 under the preservation-of-operating-profit scenario.

At TSL 3 (*i.e.,* the Recommended TSL), the standard reflects a set of efficiency levels between the levels designated in TSL 2 and TSL 4. The change in INPV is expected to range from −6.8 to −5.7 percent. At this level, free cash flow is estimated to decrease 55.2 percent compared to the no-new-standards case value of $136.6 million in the year 2027, the year before the 2028 standards year. DOE's shipments analysis estimates approximately 48 percent of current shipments meet this level.

The design options analyzed for electric standard, electric compact (120V), vented electric compact (240V), and vented gas standard include implementing electronic controls, optimized heating systems, more advanced automatic termination controls, and modulating heat. For ventless electric compact (240V) and ventless electric combination washer-dryer, the design options analyzed are the same as TSL 2. For electric standard, electric compact (120V), and vented electric compact (240V), TSL 3 corresponds to EL 4. For vented gas standard, TSL 3 corresponds to EL 3. For ventless electric compact (240V) and ventless electric combination washer-dryer, TSL 3 corresponds to EL 1. The incremental increase in industry conversion costs from the prior TSL are due to the higher efficiency level requirements for electric standard, electric compact (120V), vented electric compact (240V), and vented gas standard. Capital conversion costs may be necessary as manufacturers increase tooling for two-stage heating systems. Product conversion costs may be necessary for prototyping and testing. DOE expects industry to incur similar re-flooring costs as with TSL 2. DOE estimates capital conversion costs of $128.9 million and product conversion costs of $51.7 million. Conversion costs total $180.7 million.

At TSL 3, the shipment-weighted average MPC for all consumer clothes dryers is expected to increase by 1.7 percent relative to the no-new-standards case shipment-weighted average MPC for all consumer clothes dryers in 2028. Given the relatively small increase in production costs, DOE does not project a notable drop in shipments in the year the standard takes effect. In the preservation-of-gross-margin-percentage scenario, the increase in cash flow from the higher MSP is outweighed by the $180.7 million in conversion costs, causing a negative change in INPV at TSL 3 under this scenario. Under the preservation-of-operating-profit scenario, the manufacturer markup decreases in 2029, the year after the analyzed 2028 compliance year. This reduction in the manufacturer markup and the $180.7 million in conversion costs incurred by manufacturers cause a negative change in INPV at TSL 3 under the preservation-of-operating-profit scenario.

At TSL 4, the standard reflects the maximum national energy savings with a simple PBP of less than 4 years. The change in INPV is expected to range from −29.0 to −18.5 percent. At this level, free cash flow is estimated to decrease by 212.5 percent compared to the no-new-standards case value of $136.7 million in the year 2026, the year before the 2027 standards year. DOE's shipments analysis estimates approximately 15 percent of current shipments meet this level.

The design options analyzed for electric standard include implementing electronic controls, optimized heating systems, more advanced automatic termination controls, modulating heat, and inlet air preheat. For the remaining product classes, the efficiency levels and analyzed design options for TSL 4 are the same as TSL 3. The incremental increase in industry conversion costs from the prior TSL is due to the efficiency level requirements for electric standard. There is very little industry experience with inlet air preheat designs. Currently, DOE is not aware of any consumer clothes dryers on the market utilizing this design option. Electric standard dryers account for an estimated 81 percent of domestic consumer clothes dryer shipments. Of these standard electric dryer shipments, DOE estimates only 7 percent meet or exceed the efficiency level required by TSL 4. Implementing inlet air preheat represents a major overhaul of existing product lines and manufacturing facilities. For capital conversion costs, this change might necessitate significant new equipment and tooling. Product conversion costs may be necessary for designing, prototyping, and testing new or updated platforms. DOE expects industry to incur more re-flooring costs compared to prior TSLs as more display units would need to be replaced with high-efficiency models. DOE estimates capital conversion costs of $579.7 million and product conversion costs of $87.7 million. Conversion costs total $667.5 million.

At TSL 4, the large conversion costs result in free cash flow dropping below zero in the years before the standards year. The negative free cash-flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At this level, the shipment-weighted average MPC for all consumer clothes dryers is expected to increase by 13 percent relative to the no-new-standards case shipment-weighted average MPC for all consumer clothes dryers in 2027. Given the projected increase in production costs, DOE estimates a less than 1-percent drop in shipments in the year the standard takes effect compared to the no-new-standards case. In the preservation-of-gross-margin-percentage scenario, the increase in cash flow from the higher MSP is outweighed by the $667.5 million in conversion costs, causing a negative change in INPV at TSL 4 under this scenario. Under the preservation-of-operating-profit scenario, the manufacturer markup decreases in 2028, the year after the analyzed 2027 compliance year. This reduction in the manufacturer markup and the $667.5 million in conversion costs incurred by manufacturers cause a negative change in INPV at TSL 4 under the preservation-of-operating-profit scenario.

At TSL 5, the standard reflects the maximum national energy savings with maximum positive NPV. The change in INPV is expected to range from −67.9 to −14.9 percent. At this level, free cash flow is estimated to decrease by 462.9 percent compared to the no-new-standards case value of $136.7 million in the year 2026, the year before the 2027 standards year. DOE's shipments analysis estimates approximately 2 percent of current shipments meet this level.

The design option analyzed for electric standard includes implementing heat pump technology. The design options analyzed for the vented electric compact (240V) and vented gas standard include implementing electronic controls, optimized heating systems, more advanced automatic termination controls, modulating heat, and inlet air preheat. For electric compact (120V), ventless electric compact (240V), and ventless electric combination washer-

dryer, the design options analyzed are the same as the prior TSL. For electric standard, TSL 5 corresponds to EL 7. For electric compact (120V) and vented gas standard, TSL 5 corresponds to EL 4. For vented electric compact (240V), TSL 5 corresponds to EL 5. For ventless electric compact (240V) and ventless electric combination washer-dryer, TSL 5 corresponds to EL 1.

At TSL 5, conversion costs are largely driven by the max-tech efficiency level required for electric standard and vented gas standard. As previously discussed, electric standard dryers account for 81 percent of domestic consumer clothes dryer shipments. Currently, there are few electric standard models on the U.S. market that meet the max-tech efficiency level required by TSL 5. Of the 13 OEMs identified that offer electric standard dryers, only five OEMs manufacture electric standard dryers that utilize heat pump technology. Of these five OEMs, four OEMs offer approximately six models (accounting for less than 1 percent of electric standard model listings) that meet the max-tech level required at TSL 5. Nearly all manufacturers would need to significantly update facilities to meet a heat pump efficiency level for electric standard dryers. Mandating a heat pump efficiency level for this product class would require many manufacturers to design completely new clothes dryer platforms or adapt heat pump designs from other markets (*i.e.,* redesign European heat pump models to adhere to U.S. safety standards and consumer preferences).

Vented gas standard dryers account for approximately 17 percent of domestic consumer clothes dryer shipments. Manufacturers would need to implement inlet air preheat technology along with other design options to meet the efficiency levels required by TSL 5. Thus far, dryers with this technology and performance have not been observed in clothes dryers available on the consumer market. Clothes dryers with inlet air preheat designs have been observed only in laboratory settings. In interviews, some manufacturers raised concerns about implementing a relatively untested technology for the consumer market. There is very little industry experience with inlet air preheat designs. Several manufacturers speculated that implementing inlet air preheat technology would require a major overhaul of existing production facilities and a significant amount of engineering time.

DOE expects industry to incur more re-flooring costs compared to prior TSLs, as nearly all display units would need to be replaced with high-efficiency models. DOE estimates capital conversion costs of $1,314.3 million and product conversion costs of $122.6 million. Conversion costs total $1,436.9 million.

As with TSL 4, the large conversion costs result in free cash flow dropping below zero in the years before the standard year. The negative free cash-flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At this level, the shipment-weighted average MPC for all consumer clothes dryers is expected to increase by 63.2 percent relative to the no-new-standards case shipment-weighted average MPC for all consumer clothes dryers in 2027. Given the projected increase in production costs, DOE expects an estimated 11-percent drop in shipments in the year the standard takes effect compared to the no-new-standards case. In the preservation-of-gross-margin-percentage scenario, the increase in MSP is outweighed by the $1,436.9 million in conversion costs and the drop in annual shipments, causing a negative change in INPV at TSL 5 under this scenario. Under the preservation-of-operating-profit scenario, the manufacturer markup decreases in 2028, the year after the analyzed 2027 compliance year. This large reduction in manufacturer markup, the $1,436.9 million in conversion costs incurred by manufacturers, and the drop in annual shipments cause a significantly negative change in INPV at TSL 5 under the preservation-of-operating-profit scenario.

At TSL 6, the standard reflects max-tech efficiency for all product classes. The change in INPV is expected to range from −71.4 to −17.1 percent. At this level, free cash flow is estimated to decrease by 488.8 percent compared to the no-new-standards case value of $136.7 million in the year 2026, the year before the 2027 standards year. DOE's shipments analysis estimates approximately 1 percent of current shipments meet this level.

The design option analyzed for TSL 6 incorporates heat pump technology for electric standard, electric compact (120V), vented electric compact (240V), ventless electric compact (240V), and ventless electric combination washer-dryer. For vented gas standard, the design options analyzed include implementing electronic controls, optimized heating systems, more advanced automatic termination controls, modulating heat, and inlet air preheat.

Of the 19 OEMs that manufacture electric consumer clothes dryers (*i.e.,* electric standard, electric compact (120V), vented electric compact (240V), ventless electric compact (240V), ventless electric combination washer-dryer), 10 OEMs do not currently offer any consumer clothes dryer models for the U.S. market that utilize heat pump technology. Of the 13 OEMs that offer electric standard clothes dryers, four OEMs currently offer some models that meet the max-tech heat pump level. Of the 10 OEMs that offer electric compact (120V) clothes dryers, one OEM offers a model that meets the max-tech level. Of the five OEMs that offer vented electric compact (240V) clothes dryers, one OEM offers models that meet the max-tech level. Of the 13 OEMs that offer ventless electric compact (240V) clothes dryers, one OEM offers a model that meets the max-tech level. Of the five OEMs that offer ventless electric combination washer-dryer, two OEMs offer models that meet the max-tech level.

A standard that could only be met using heat pump technology could require a total renovation of existing facilities and completely new clothes dryer platforms for manufacturers that do not offer heat pump clothes dryers today. In interviews, two OEMs with significant market shares stated that they would require additional facilities to handle dryer manufacturing under a standard that could only be met using heat pump technology. As previously discussed, implementing inlet air preheat also represents a major overhaul of existing vented gas product lines. DOE expects industry to incur slightly more re-flooring costs compared to TSL 5, as all display models below max-tech efficiency would need to be replaced due to the higher standard. At TSL 6, reaching max-tech efficiency levels is a billion-dollar investment for industry. DOE estimates capital conversion costs of $1,388.8 million and product conversion costs of $128.2 million. Conversion costs total $1,516.9 million.

As with TSL 4 and TSL 5, the large conversion costs result in free cash flow dropping below zero in the years before the standard year. The negative free cash-flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At this level, the shipment-weighted average MPC for all consumer clothes dryers is expected to increase by 64.7 percent relative to the no-new-standards case shipment-weighted average MPC for all consumer clothes dryers in 2027. Given the projected increase in production costs, DOE expects an

estimated 11-percent drop in shipments in the year the standard takes effect compared to the no-new-standards case. In the preservation-of-gross-margin-percentage scenario, the large increase in MSP is still outweighed by the $1,516.9 million in conversion costs and drop in annual shipments, causing a moderately negative change in INPV at TSL 6 under this scenario. Under the preservation-of-operating-profit scenario, the manufacturer markup decreases in 2028, the year after the analyzed 2027 compliance year. This large reduction in manufacturer markup, the $1,516.9 million in conversion costs incurred by manufacturers, and the drop in annual shipments cause a significantly negative change in INPV at TSL 6 under the preservation-of-operating-profit scenario.

b. Direct Impacts on Employment

To quantitatively assess the potential impacts of amended energy conservation standards on direct employment in the consumer clothes dryer industry, DOE used the GRIM to estimate the domestic labor expenditures and number of direct employees in the no-new-standards case and in each of the standards cases during the analysis period. For the direct final rule, DOE used the most up-to-date information available. DOE calculated these values using statistical data from the U.S. Census Bureau's 2021 ASM,[117] the U.S. Bureau of Labor Statistics' employee compensation data,[118] results of the engineering analysis, and manufacturer interviews.

Labor expenditures related to product manufacturing depend on the labor intensity of the product, the sales volume, and an assumption that wages remain fixed in real terms over time. The total labor expenditures in each year are calculated by multiplying the total MPCs by the labor percentage of MPCs. The total labor expenditures in the GRIM were then converted to total production employment levels by dividing production labor expenditures by the average fully burdened wage multiplied by the average number of hours worked per year per production worker. To do this, DOE relied on ASM inputs: Production Workers Annual Wages, Production Workers Annual Hours, Production Workers for Pay Period, and Number of Employees. DOE also relied on BLS employee compensation data to determine the fully burdened wage ratio. The fully burdened wage ratio factors in paid leave, supplemental pay, insurance, retirement and savings, and legally required benefits.

The number of production employees is then multiplied by the U.S. labor percentage to convert total production employment to total domestic production employment. The U.S. labor percentage represents the industry fraction of domestic manufacturing production capacity for the covered product. This value is derived from manufacturer interviews, product database analysis, and publicly available information. For the August 2022 NOPR, DOE estimated that approximately 58 percent of consumer clothes dryers were produced domestically. In support of this direct final rule analysis, DOE conducted further research to ensure this estimate was still accurate. Based on a review of publicly available data, DOE estimates that 60 percent of consumer clothes dryers are produced domestically.

The domestic production employees estimate covers production line workers, including line supervisors, who are directly involved in fabricating and assembling products within the OEM facility. Workers performing services that are closely associated with production operations, such as materials-handling tasks using forklifts, are also included as production labor. DOE's estimates only account for production workers who manufacture the specific products covered by this amended rulemaking.

Non-production workers account for the remainder of the direct employment figure. The non-production employees estimate covers domestic workers who are not directly involved in the production process, such as sales, engineering, human resources, and management. Using the amount of domestic production workers calculated above, non-production domestic employees are extrapolated by multiplying the ratio of non-production workers in the industry compared to production employees. DOE assumes that this employee distribution ratio remains constant between the no-new-standards case and standards cases.

Using the GRIM, DOE estimates that in the absence of new energy conservation standards, there would be 2,725 domestic production and non-production workers for consumer clothes dryers in 2027. Table V.28 shows the range of the impacts of energy conservation standards on U.S. manufacturing employment in the consumer clothes dryer industry. The following discussion provides a qualitative evaluation of the range of potential impacts presented in Table V.28.

TABLE V.28—DOMESTIC DIRECT EMPLOYMENT IMPACTS FOR CONSUMER CLOTHES DRYER MANUFACTURERS IN THE ANALYZED COMPLIANCE YEAR

	No-new-standards case	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Direct Employment in 2027* (Production Workers + Non-Production Workers).	**2,725	2,729	2,752	2,778	3,106	5,687	5,737
Potential Changes in Direct Employment Workers***.		(2,433) to 4	(2,433) to 27	(2,433) to 34	(2,433) to 381	(2,433) to 2,962	(2,433) to 3,012

*TSL 3 (the Recommended TSL) represents the direct employment in 2028.
**In 2028, the no-new-standards case direct employment estimate is 2,744.
***DOE presents a range of potential employment impacts. Parentheses denote negative values.

The direct employment impacts shown in Table V.29 represent the potential domestic employment changes that could result following the compliance date for the consumer clothes dryer product classes in this amended rule. The upper-bound estimate corresponds to an increase in the number of domestic workers that would result from amended energy conservation standards if manufacturers continue to produce the same scope of

[117] U.S. Census Bureau, Annual Survey of Manufactures: Summary Statistics for Industry Groups and Industries in the U.S.: 2018–2021. Available at *www.census.gov/programs-surveys/asm/data/tables.html* (last accessed May 23, 2023).

[118] U.S. Bureau of Labor Statistics. *Employer Costs for Employee Compensation*. March 17, 2023. Available at *www.bls.gov/news.release/pdf/ecec.pdf* (last accessed June 8, 2023).

covered products within the United States after compliance takes effect. The lower-bound estimate represents the maximum decrease in production workers if manufacturing moved to lower labor-cost countries. Most manufacturers currently produce at least a portion of their consumer clothes dryers in countries with lower labor costs, and an amended standard that necessitates large increases in labor content or large expenditures to retool facilities could cause manufacturers to reevaluate domestic production siting options. However, the Recommended TSL (*i.e.,* TSL 3) would likely not require significant increases in labor content or significant capital investments. As such, DOE expects that the likelihood of changes in production location as a direct result of amended standards are relatively low.

Additional detail on the analysis of direct employment can be found in chapter 12 of the direct final rule TSD. Additionally, the employment impacts discussed in this section are independent of the employment impacts from the broader U.S. economy, which are documented in chapter 16 of the direct final rule TSD.

c. Impacts on Manufacturing Capacity

As discussed in section V.B.2.a of this document, implementing the different design options analyzed for this direct final rule would require varying levels of resources and investment. A standard level that would require the use of heat pump technology for electric dryers and combination washer-dryers would represent the biggest shift in technology for clothes dryer manufacturing among all the design options considered for this analysis. Adopting efficiency levels that require heat pump technology would necessitate very large investments to both redesign products and update production facilities. Currently, DOE estimates that approximately 1 percent of consumer clothes dryer shipments meet the analyzed max-tech heat pump efficiency levels. In interviews, several manufacturers expressed concern that the 3-year EPCA-specified time period between the announcement of a final rule and the compliance date of the amended energy conservation standard might be insufficient to design, test, and manufacture the necessary number of products to meet demand.

In interviews, some manufacturers raised concerns about implementing inlet air preheat designs. Unlike the discussions about heat pump technology, there is very little industry experience with inlet air preheat designs. Currently, no models on the U.S. market incorporate this design option. Several manufacturers speculated that implementing inlet air preheat would require a major overhaul of existing production facilities and a significant amount of engineering time.

However, because TSL 3 (*i.e.,* the Recommended TSL) would not require heat pump technology or inlet air preheat designs, DOE does not expect manufacturers to face long-term capacity constraints due to the standard levels detailed in this direct final rule. Furthermore, at the Recommended TSL, manufacturers will have a 4-year period between the announcement of the direct final rule and the compliance date of the amended energy conservation standards to redesign products to meet the adopted standard levels.

d. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop industry cash flow estimates may not capture the differential impacts among subgroups of manufacturers. Small manufacturers, niche players, or manufacturers exhibiting a cost structure that differs substantially from the industry average could be affected disproportionately. DOE investigated small businesses as a manufacturer subgroup that could be disproportionally impacted by energy conservation standards and could merit additional analysis. DOE did not identify any other adversely impacted manufacturer subgroups for this rulemaking based on the results of the industry characterization.

DOE analyzes the impacts on small businesses in a separate analysis for the standards proposed in the NOPR published elsewhere in this issue of the **Federal Register** and in chapter 12 of the direct final rule TSD. For a discussion of the impacts on the small business manufacturer subgroup, *see* chapter 12 of the direct final rule TSD.

e. Cumulative Regulatory Burden

One aspect of assessing manufacturer burden involves looking at the cumulative impact of multiple DOE standards and the regulatory actions of other Federal agencies and States that affect the manufacturers of a covered product or equipment. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

For the cumulative regulatory burden analysis, DOE examines Federal, product-specific regulations that could affect consumer clothes dryer manufacturers that take effect approximately 3 years before or after the 2028 compliance date. This information is presented in Table V.29.

TABLE V.29—COMPLIANCE DATES AND EXPECTED CONVERSION EXPENSES OF FEDERAL ENERGY CONSERVATION STANDARDS AFFECTING CONSUMER CLOTHES DRYER ORIGINAL EQUIPMENT MANUFACTURERS

Federal energy conservation standard	Number of OEMs *	Number of OEMs affected by today's rule **	Approx. standards compliance year	Industry conversion costs (Millions)	Industry conversion costs/equipment revenue ***(%)
Portable Air Conditioners 85 FR 1378 (January 10, 2020)	9	2	2025	$320.9 (2015$)	6.7
Residential Clothes Washers †88 FR 13520 (March 3, 2023)	19	14	2027	$690.8 (2021$)	5.2
Miscellaneous Refrigeration Products †88 FR 19382 (March 31, 2023)	38	5	2029	$126.9 (2021$)	3.1
Automatic Commercial Ice Makers †88 FR 30508 (May 11, 2023)	23	1	2027	$15.9 (2022$)	0.6
Dishwashers †88 FR 32514 (May 19, 2023)	21	12	2027	$125.6 (2021$)	2.1

TABLE V.29—COMPLIANCE DATES AND EXPECTED CONVERSION EXPENSES OF FEDERAL ENERGY CONSERVATION STANDARDS AFFECTING CONSUMER CLOTHES DRYER ORIGINAL EQUIPMENT MANUFACTURERS—Continued

Federal energy conservation standard	Number of OEMs *	Number of OEMs affected by today's rule **	Approx. standards compliance year	Industry conversion costs (Millions)	Industry conversion costs/equipment revenue ***(%)
Refrigerated Bottled or Canned Beverage Vending Machines †88 FR 33968 (May 25, 2023)	5	1	2028	$1.5 (2022$)	0.2
Room Air Conditioners 88 FR 34298 (May 26, 2023)	8	4	2026	$24.8 (2021$)	0.4
Microwave Ovens 88 FR 39912 (June 20, 2023)	18	11	2026	$46.1 (2021$)	0.7
Consumer Water Heaters †88 FR 49058 (July 28, 2023)	22	3	2030	$228.1 (2022$)	1.3
Commercial Water Heating Equipment 88 FR 69686 (October 6, 2023)	15	1	2026	$42.7 (2022$)	5.3
Commercial Refrigerators, Refrigerator-Freezers, and Freezers †88 FR 70196 (October 10, 2023)	83	4	2028	$226.4 (2022$)	1.6
Dehumidifiers †88 FR 76510 (November 6, 2023)	20	3	2028	$6.9 (2022$)	0.4
Consumer Furnaces 88 FR 87502 (December 18, 2023)	15	1	2029	$162.0 (2022$)	1.8
Refrigerators, Freezers, and Refrigerator-Freezers 89 FR 3026 (January 17, 2024)	63	11	‡2029 and 2030	$830.3 (2022$)	1.3
Consumer Conventional Cooking Products 89 FR 11434 (February 14, 2024)	35	8	2028	$66.7 (2022$)	0.3

* This column presents the total number of OEMs identified in the energy conservation standard rule that is contributing to cumulative regulatory burden.

** This column presents the number of OEMs producing consumer clothes dryers that are also listed as OEMs in the identified energy conservation standard that is contributing to cumulative regulatory burden.

*** This column presents industry conversion costs as a percentage of equipment revenue during the conversion period. Industry conversion costs are the upfront investments manufacturers must make to sell compliant products/equipment. The revenue used for this calculation is the revenue from just the covered product/equipment associated with each row. The conversion period is the time frame over which conversion costs are made and lasts from the publication year of a final rule to the compliance year of the energy conservation standard. The conversion period typically ranges from 3 to 5 years, depending on the rulemaking.

† These rulemakings are at the NOPR stage, and all values are subject to change until finalized through publication of a final rule.

‡ For the refrigerators, refrigerator-freezers, and freezers energy conservation standards direct final rule, the compliance year (2029 or 2030) varies by product class.

As shown in Table V.29, the rulemakings with the largest overlap of consumer clothes dryer OEMs include residential clothes washers, consumer conventional cooking products, dishwashers, refrigerators, refrigerator-freezers, and freezers, and miscellaneous refrigeration products, which are all part of the multi-product Joint Agreement submitted by interested parties.[119] As detailed in the Joint Agreement, the signatories indicated that their recommendations should be considered a ''complete package.'' The signatories further stated that ''each part of this agreement is contingent upon the other parts being implemented.'' (Joint Agreement, No. 55, p. 3)

The multi-product Joint Agreement states the ''jointly recommended compliance dates will achieve the overall energy and economic benefits of this agreement while allowing necessary lead-times for manufacturers to redesign products and retool manufacturing plants to meet the recommended standards across product categories.'' (Joint Agreement, No. 55 at p. 2) The staggered compliance dates help mitigate manufacturers' concerns about their ability to allocate sufficient resources to comply with multiple concurrent amended standards and about the need to align compliance dates for products that are typically designed or sold as matched pairs (such as residential clothes washers and consumer clothes dryers). *See* section IV.J.3 of this document for stakeholder comments about cumulative regulatory burden. *See* Table V.30 for a comparison of the estimated compliance dates based on EPCA-specified timelines and the compliance dates detailed in the Joint Agreement.

TABLE V.30—EXPECTED COMPLIANCE DATES FOR MULTI-PRODUCT JOINT AGREEMENT

Rulemaking	Estimated compliance year based on EPCA requirements	Compliance year in the joint agreement
Consumer Clothes Dryers	2027	2028
Residential Clothes Washers	2027	2028
Consumer Conventional Cooking Products	2027	2028

[119] The microwave ovens energy conservation standards final rule (88 FR 39912), which has 11 overlapping OEMs, was published prior to the joint submission of the multi-product Joint Agreement.

TABLE V.30—EXPECTED COMPLIANCE DATES FOR MULTI-PRODUCT JOINT AGREEMENT—Continued

Rulemaking	Estimated compliance year based on EPCA requirements	Compliance year in the joint agreement
Dishwashers	2027	2027 *
Refrigerators, Refrigerator-Freezers, and Freezers	2027	2029 or 2030 depending on the product class.
Miscellaneous Refrigeration Products	2029	2029

* Estimated compliance year. The Joint Agreement states, ''3 years after the publication of a final rule in the **Federal Register**.'' (Joint Agreement, No. 55 at p. 2)

3. National Impact Analysis

This section presents DOE's estimates of the national energy savings and the NPV of consumer benefits that would result from each of the TSLs considered as potential amended standards.

a. Significance of Energy Savings

To estimate the energy savings attributable to potential amended standards for consumer clothes dryers, DOE compared clothes dryer energy consumption under the no-new-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the year of anticipated compliance with amended standards (2027–2056).[120] Table V.31 presents DOE's projections of the national energy savings for each TSL considered for consumer clothes dryers. The savings were calculated using the approach described in section IV.H.2 of this document.

TABLE V.31—CUMULATIVE NATIONAL ENERGY SAVINGS FOR CONSUMER CLOTHES DRYERS; 30 YEARS OF SHIPMENTS (2027–2056) *

	Trial Standard Level					
	1	2	3	4	5	6
	quads					
Primary energy	0.55	1.53	2.57	3.41	9.42	9.47
FFC energy	0.57	1.58	2.66	3.52	9.70	9.76

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

OMB Circular A–4 requires agencies to present analytical results including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this rulemaking, DOE undertook a sensitivity analysis using 9 years, rather than 30 years, of product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.[121] The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to consumer clothes dryers. Thus, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.32. The impacts are counted over the lifetime of consumer clothes dryers purchased during the period 2027–2035.[122]

TABLE V.32—CUMULATIVE NATIONAL ENERGY SAVINGS FOR CONSUMER CLOTHES DRYERS; 9 YEARS OF SHIPMENTS (2027–2035) *

	Trial Standard Level					
	1	2	3	4	5	6
	quads					
Primary energy	0.19	0.54	0.92	1.17	2.80	2.81

[120] The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

[121] EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6-year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

[122] The analysis period for TSL 3 (the Recommended TSL) is 2028–2036.

TABLE V.32—CUMULATIVE NATIONAL ENERGY SAVINGS FOR CONSUMER CLOTHES DRYERS; 9 YEARS OF SHIPMENTS (2027–2035) *—Continued

	Trial Standard Level					
	1	2	3	4	5	6
	quads					
FFC energy	0.20	0.56	0.96	1.21	2.89	2.90

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2036.

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from the TSLs considered for consumer clothes dryers. In accordance with OMB's guidelines on regulatory analysis, DOE calculated NPV using both a 7-percent and a 3-percent real discount rate. Table V.33 shows the consumer NPV results with impacts counted over the lifetime of products purchased during the period 2027–2056.

TABLE V.33—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR CONSUMER CLOTHES DRYERS; 30 YEARS OF SHIPMENTS (2027–2056) *

	Trial Standard Level					
	1	2	3	4	5	6
	billion 2022$					
3 percent	4.07	12.33	20.08	19.85	31.21	30.50
7 percent	1.92	5.88	9.23	8.42	9.03	8.58

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.34. The impacts are counted over the lifetime of products purchased during the period 2027–2035. As mentioned previously, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology or decision criteria.

TABLE V.34 CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR CONSUMER CLOTHES DRYERS; 9 YEARS OF SHIPMENTS (2027–2035) *

	Trial Standard Level					
	1	2	3	4	5	6
	billion 2022$					
3 percent	1.78	5.46	9.08	8.80	13.64	13.41
7 percent	1.07	3.31	5.28	4.77	5.69	5.49

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2036.

The previous results reflect the use of a default trend to estimate the change in price for consumer clothes dryers over the analysis period (*see* section IV.F.1 of this document). DOE also conducted a sensitivity analysis that considered one scenario with a lower rate of price decline than the reference case and one scenario with a higher rate of price decline than the reference case. The results of these alternative cases are presented in appendix 10C of the direct final rule TSD. In the high-price-decline case, the NPV of consumer benefits is higher than in the default case. In the lower-price-decline case, the NPV of consumer benefits is lower than in the default case.

c. Indirect Impacts on Employment

DOE estimates that amended energy conservation standards for consumer clothes dryers will reduce energy expenditures for consumers of those products, with the resulting net savings being redirected to other forms of economic activity. These expected shifts in spending and economic activity could affect the demand for labor. As described in section IV.N of this document, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered. There are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term timeframes (2027–2033),[123] where these uncertainties are reduced.

The results suggest that the adopted standards are likely to have a negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on employment. Chapter 16 of the direct final rule TSD presents detailed results regarding anticipated indirect employment impacts.

[123] The analysis period for TSL 3 (the Recommended TSL) is 2028–2034.

4. Impact on Utility or Performance of Products

As discussed in section III.E.1.d of this document, DOE has concluded that the standards adopted in this direct final rule will not lessen the utility or performance of the consumer clothes dryers under consideration in this rulemaking. Manufacturers of these products currently offer units that meet or exceed the adopted standards.

In response to the August 2022 NOPR, AHAM stated that DOE must ensure that amended standards do not lengthen cycle times, and AHAM believes that in order to achieve the test procedure's current FMC requirement and meet the standards proposed in the August 2022 NOPR, cycle lengths will get longer. Whirlpool commented that the strategies used in consumer clothes dryers certified under appendix D2 often lower the overall average drying temperature and extend the drying time to increase the CEF, while minimally compliant consumer clothes dryers certified under appendix D1 typically achieve a higher overall temperature and shorten the drying process. Citing DOE's test sample, Whirlpool stated that models certified using appendix D1 without wrinkle prevention mode activated had an average drying time of 56 minutes when tested to appendix D2, while models certified using appendix D2 had an average drying time of 66 minutes, and ENERGY STAR-qualified products had an average drying time of 71 minutes, the additional time needed to meet the 2-percent FMC requirement. Whirlpool stated that DOE's statutory criteria are not met to proceed with the standards proposed in the August 2022 NOPR due to a clear lessening of performance and utility of the product associated with longer drying times. (AHAM, No. 46 at pp. 8–10; Whirlpool, No. 53 at p. 4)

DOE's test data do not support the assertion by AHAM and Whirlpool that amended standards would necessitate longer drying times. In DOE's test sample, the consumer clothes dryers certified under appendix D1 have an average cycle time of 61 minutes when tested in accordance with appendix D2. In comparison, among the units in DOE's test sample that are certified under appendix D2 at or above the amended standard, multiple units have a cycle time less than 60 minutes. This indicates that the standards adopted by this direct final rule will not necessitate any increase in cycle time compared to typical cycle times currently associated with baseline consumer clothes dryers. DOE notes that a 60-minute cycle time is notably less than the 80-minute cycle time required for ENERGY STAR qualification.[124] DOE further notes that cycle time is one of many product attributes that consumers consider when purchasing a clothes dryer, such as drying performance and fabric care. As further examples, Consumer Reports—which DOE recognizes is one popular resource for consumers seeking independent reviews of consumer products—highlights the following product attributes for consumer clothes dryers in addition to cycle time: drying performance, ergonomics, noise level, capacity, drum material, compatibility with a drying rack, availability of custom programs, availability of a steam option, moisture sensing capability, Wifi connectivity, and stackability with an accompanying clothes washer.[125]

As noted in section IV.H.2 of this document, DOE has observed a steady decline in annual consumer clothes dryer cycles over the past 15 years, despite the implementation of more stringent consumer clothes dryer energy conservation standards, which is an indication that consumers are not rerunning their clothes dryers. Additionally, the amended standards correspond to the current ENERGY STAR efficiency level for both electric and gas standard clothes dryers, which requires testing in accordance with appendix D2 and which ensures consumer-accepted dryness levels as discussed in section II.B.2 of this document. As noted above, DOE does not expect increased cycle times compared to typical cycle times currently associated with baseline consumer clothes dryers as a result of adopted standards. In addition, DOE does not expect consumers to re-run the consumer clothes dryer upon completion of the initial run as a result of the amended standards being adopted in this direct final rule. DOE therefore does not expect a lessening in performance or utility as a result of the standards adopted by this direct final rule. As previously discussed, on February 14, 2024, DOE received a second joint statement from the same group of stakeholders that submitted the Joint Agreement in which the signatories reaffirmed the standards recommended in the Joint Agreement.[126] In particular, the letter states that DOE's test data show, and industry experience agrees, that the recommended standard levels for consumer clothes dryers will not result in significant differences in cycle time and will adequately dry clothes.

Whirlpool stated that due to the core technological differences in energy-saving heat pump clothes dryers (such as lower air temperatures, heat retention, and water condensing systems) compared to conventional resistive heater clothes dryers, harder-to-dry fabrics need additional time in a heat pump clothes dryer to remove their embedded moisture and some heat pump clothes dryers may not get down to the required FMC. (Whirlpool, No. 53 at pp. 12–13)

With regard to Whirlpool's concerns about the performance of heat pump clothes dryers for certain hard-to-dry fabrics, DOE notes that the standards adopted by this direct final rule do not require the use of heat pump technology. AHAM stated that longer consumer clothes dryer cycle times may create different cycle times between clothes washers and clothes dryers, which may result in different consumer behaviors. According to AHAM, different operating times in laundry products may result in the increased use of wrinkle control cycles or redrying loads to avoid wrinkled clothes resulting from the clothes sitting in the clothes dryer for more extended periods of time, or in consumers re-washing clothes that were not transferred to the clothes dryer due to a previous load still being dried, ultimately resulting in increased water and energy use. AHAM also stated that consumers could turn to using other cycles, thus undercutting savings designed to be achieved through use of the normal cycle. AHAM and Whirlpool therefore stated that DOE should evaluate the impact of amended standards on drying times as cycle length is a performance feature associated with consumer preferences that consumers are unlikely to accept if cycles are too long and do not match washing times. AHAM also disagreed with DOE's use of the maximum drying time of 80 minutes in the current ENERGY STAR specification as a benchmark for its analysis, asserting that the specification was not based on sufficient supporting or consumer-relevant data. (AHAM, No. 46 at pp. 8–10)

As previously stated, DOE does not expect a shift in consumer drying times associated with amended standards beyond what is typically experienced by consumers of baseline consumer clothes dryers. Additionally, DOE does not expect that the amended standards

[124] ENERGY STAR criteria for consumer clothes dryers can be found at: *www.energystar.gov/products/appliances/clothes_dryers/key_product_criteria.*

[125] Consumer Reports ratings of consumer clothes dryers available at *www.consumerreports.org/appliances/clothes-dryers* (last accessed February 5, 2024).

[126] This document is available in the docket at: *www.regulations.gov/comment/EERE–2014-BT-STD-0058-0058.*

would result in longer drying cycles given the prevalence on the market of consumer clothes dryers that meet the amended standard with cycle times comparable to those of current baseline models, regardless of the longer cycle time of 80 minutes allowed in the ENERGY STAR specification. Therefore, DOE has no basis to conclude that the amended standards would alter the existing relative cycle times between consumer clothes dryers and clothes washers.

The test data presented in the August 2022 NOPR contradict certain conclusions and presumptions made by DOE in previous rulemakings with regard to cycle times. In particular, in a NOPR published on August 13, 2020 (''August 2020 NOPR''), which preceded the December 2020 Final Rule, DOE stated its presumption that the shortest possible cycle times currently available on the market represent the models for which certain manufacturers have prioritized cycle time while maintaining adequate drying performance and other performance aspects of consumer clothes dryers; and that based on this presumption, the current energy conservation standards may have discouraged manufacturers from bringing models to the market with cycle times of 30 minutes or less. 85 FR 49297, 49305 reiterated at 85 FR 81359, 81361. DOE further asserted that offering products with shorter cycle times would require more per-cycle energy use than would be permitted under the current standards in order to maintain the same level of performance in other areas. 85 FR 49297, 49299.

DOE has determined, contrary to the August 2020 NOPR's assumptions, that current energy conservation standards have not prevented the sale of consumer clothes dryers with shorter cycle times. DOE's test data presented in the August 2022 NOPR indicate no discernable correlation between efficiency level and cycle time for vented electric standard dryers or vented gas clothes dryers (*i.e.,* the consumer clothes dryer product classes subject to the December 2020 Final Rule) Indeed, for vented electric standard clothes dryers, the most efficient model in DOE's test sample has a shorter cycle time (80 minutes) than the least efficient minimally-compliant model in DOE's test sample (98 minutes). The models with the lowest cycle times of 36 and 39 minutes both achieve higher efficiency level EL 3. Similarly, for vented gas clothes dryers, the most efficient model in DOE's test sample has a cycle time of 66 minutes, substantially similar to the baseline unit with a cycle time of 65 minutes. The models with the lowest cycle times of 35 and 36 minutes both achieve higher efficiency level EL 2. Based on this data, DOE reaches a different conclusion than was reached in the December 2020 Final Rule. In particular, noting that DOE's data show no discernable correlation between efficiency and cycle time, this data does not support DOE's prior assertion that the current consumer clothes dryer energy conservation standards may be precluding manufacturers from bringing models to the market with substantially shorter cycle times, or DOE's prior presumption that offering products with shorter cycle times would require more per-cycle energy use than would be permitted under the current standards.

Furthermore, in the second joint statement submitted February 14, 2024, by the signatories of the Joint Agreement, the signatories acknowledge that DOE's investigative testing shows that there is no significant difference in cycle time between consumer clothes dryers in DOE's data set that are less efficient than the recommended standards and those that just meet the recommended standard levels. The signatories noted, for example, that the difference in average cycle time is only about 2 minutes between electric standard clothes dryers in DOE's data set that are less efficient than the recommended standard and those that just meet the recommended standard (with CEFs of 3.93 and 3.94). Moreover, the signatories stated that the electric standard clothes dryers in DOE's data set that are less efficient than the recommended standards include models with longer cycle times than those that meet the recommended standards, suggesting that cycle time is tied to more than efficiency alone.

Finally, for the reasons previously discussed, DOE has also determined that the standards adopted in this direct final rule will not result in any significant differences in drying cycle times.

AHAM and Whirlpool commented that longer cycle times also cause more wear and tear on clothing as well as on the product itself and can decrease the lifetime of the product and increase the need for repair. Whirlpool stated that longer cycles lead to consumer perception that their clothes are being damaged and potentially lead consumers to interrupt consumer clothes dryer cycles to prevent garment damage, depending on different fabric types/thicknesses. Whirlpool commented that when presented with the concept of a lower-heat and slower-drying cycle that would save energy, consumers were not enthusiastic and did not trust that such a drying strategy would prevent garment damage or match clothes washer cycle times. Whirlpool stated that, according to its provided research focused on thread removal counts on test cloth, there is the possibility of increased fabric damage with longer drying times when the test cloth is in a semi-saturated state. Whirlpool commented that every 30 minutes of drying time for semi-saturated fabric is equivalent to 2.4 times the amount of fabric damage that would have been seen with one complete wash cycle in a front-load clothes washer. Whirlpool commented that this research showed 17-percent thread removal from 7 minutes of drying under appendix D1 testing and 40-percent thread removal from 30 minutes of drying under appendix D2 testing. Whirlpool stated that according to these results, appendix D2 testing resulted in a longer drying time in which the test cloth was in a semi-saturated state, as well as 2.4 times the fabric damage as a consumer clothes dryer cycle under appendix D1 testing. According to Whirlpool, the longer the drying cycle is drawn out at lower temperatures, the more total friction and thread removal occurs as the semi-saturated clothes rub together when tumbling in the drum. Whirlpool asserted that fabric care is partially a story of cycle temperature and mechanical damage from extended drying times, and although there may be some benefit from lower temperatures, the potentially increased mechanical damage from longer cycles cannot be ignored, nor the additional cost burden associated with consumers replacing damaged or worn clothing that was not factored into DOE's analysis. AHAM stated that manufacturers would also have to plan for increased wear and tear on the product itself with more robust components; therefore, AHAM disagreed with DOE's conclusion that repair and maintenance costs would not change with the proposed standard. Both AHAM and Whirlpool stated that DOE should account for the impacts of energy conservation standards associated with increased drying times on fabric care and the additional cost burden in its analysis. (AHAM, No. 46 at pp. 9–10; Whirlpool, No. 53 at p. 5)

The fabric care data Whirlpool shared shows increased thread removal from drying under appendix D2 testing compared to testing under appendix D1 for the same unit, which according to Whirlpool is due to longer drying times when the test cloth is in a semi-saturated state. However, DOE notes that amended standards would not require any specific drying strategy (*e.g.,* longer cycle times, longer drying time at

the semi-saturated state, lower drying temperatures) to ensure the FMC requirement or amended standards are met nor preclude shorter drying times at the semi-saturated state. Additionally, DOE notes that this testing did not compare the thread removal from drying for units with different efficiencies, but rather the same unit tested under two different tests, so DOE is not aware of any data substantiating a correlation between increased efficiency and thread removal. As previously noted, appendix D2 accounts for all consumer clothes dryers with and without automatic termination control and is therefore more representative of consumer use than appendix D1, and depending on the automatic termination control system, the appendix D2 cycle time may be longer or shorter than that when testing in accordance with appendix D1. Furthermore, DOE is not aware of any information indicating that the higher efficiency levels associated with amended standards would increase cycle time beyond what is typically experienced by consumers of baseline consumer clothes dryers, and has determined that existing cycle times can be met with consumer clothes dryers capable of meeting the amended standards. Therefore, DOE has concluded the recommend standards that are the subject of this direct final rule would not result in increased impacts on fabric care and product wear and tear as AHAM and Whirlpool suggested. Additionally, DOE notes that AHAM recommended the efficiency levels proposed in the August 2022 NOPR for adoption in this direct final rule. DOE, however, will continue to review relevant data on potential impacts on fabric care and product wear and tear and may consider it in future rulemakings.

For the reasons discussed throughout this section and based on the additional confirming statements from the Joint Agreement signatories, DOE has concluded that the standards adopted in this direct final rule will not lessen the utility or performance of the consumer clothes dryers under consideration in this rulemaking.

5. Impact of Any Lessening of Competition

DOE considered any lessening of competition that would be likely to result from new or amended standards. As discussed in section III.E.1.e of this document, EPCA directs the Attorney General of the United States (''Attorney General'') to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination in writing to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. To assist the Attorney General in making this determination, DOE is providing the DOJ with copies of this direct final rule and the TSD for review.

6. Need of the Nation To Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts (costs) of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. Chapter 15 in the direct final rule TSD presents the estimated impacts on electricity generating capacity, relative to the no-new-standards case, for the TSLs that DOE considered in this rulemaking.

Energy conservation resulting from potential energy conservation standards for consumer clothes dryers is expected to yield environmental benefits in the form of reduced emissions of certain air pollutants and greenhouse gases. Table V.35 provides DOE's estimate of cumulative emissions reductions expected to result from the TSLs considered in this rulemaking. The emissions were calculated using the multipliers discussed in section IV.K of this document. DOE reports annual emissions reductions for each TSL in chapter 13 of the direct final rule TSD.

TABLE V.35—CUMULATIVE EMISSIONS REDUCTION FOR CONSUMER CLOTHES DRYERS SHIPPED IN 2027–2056 *

	Trial Standard Level					
	1	2	3	4	5	6
Power Sector Emissions						
CO_2 (*million metric tons*)	11.2	30.8	51.5	66.5	170.9	171.7
CH_4 (*thousand tons*)	0.7	2.0	3.3	4.4	12.0	12.1
N_2O (*thousand tons*)	0.1	0.3	0.4	0.6	1.7	1.7
NO_X (*thousand tons*)	6.4	17.4	29.3	36.6	87.6	88.0
SO_2 (*thousand tons*)	2.9	8.3	13.6	18.7	52.4	52.7
Hg (*tons*)	0.02	0.06	0.09	0.13	0.36	0.36
Upstream Emissions						
CO_2 (million metric tons)	1.2	3.3	5.6	7.0	17.7	17.8
CH_4 (thousand tons)	114.0	309.4	524.3	657.1	1,633	1,642
N_2O (thousand tons)	0.005	0.001	0.021	0.003	0.1	0.1
NO_X (thousand tons)	18.9	51.6	87.3	110.0	276.5	277.9
SO_2 (thousand tons)	0.1	0.2	0.3	0.3	1.0	1.0
Hg (tons)	0.0001	0.0002	0.0003	0.0005	0.0013	0.0013
Total FFC Emissions						
CO_2 (*million metric tons*)	12.4	34.1	57.1	73.5	188.6	189.5
CH_4 (*thousand tons*)	114.7	311.4	527.6	661.5	1,645	1,654
N_2O (*thousand tons*)	0.1	0.3	0.5	0.6	1.7	1.7
NO_X (*thousand tons*)	25.4	69.0	116.5	146.6	364.1	365.9
SO_2 (*thousand tons*)	3.0	8.4	13.9	19.0	53.3	53.6
Hg (*tons*)	0.02	0.06	0.10	0.13	0.36	0.37

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

As part of the analysis for this rule, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 that DOE estimated for each of the considered TSLs for consumer clothes dryers. Section IV.L of this document discusses the estimated SC–CO_2 values that DOE used. Table V.36 presents the value of CO_2 emissions reduction at each TSL for each of the SC–CO_2 cases. The time series of annual values is presented for the selected TSL in chapter 14 of the direct final rule TSD.

TABLE V.36—PRESENT VALUE OF CO_2 EMISSIONS REDUCTION FOR CONSUMER CLOTHES DRYERS SHIPPED IN 2027–2056 *

TSL	SC–CO_2 case discount rate and statistics			
	5% Average	3% Average	2.5% Average	3% 95th percentile
	(*million 2022$*)			
1	136	565	876	1,718
2	376	1,559	2,415	4,739
3	613	2,566	3,985	7,800
4	808	3,353	5,197	10,192
5	2,012	8,435	13,115	25,622
6	2,022	8,479	13,183	25,753

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

As discussed in section IV.L.2 of this document, DOE estimated the climate benefits likely to result from the reduced emissions of methane and N_2O that DOE estimated for each of the considered TSLs for consumer clothes dryers. Table V.37 presents the value of the CH_4 emissions reduction at each TSL, and Table V.38 presents the value of the N_2O emissions reduction at each TSL. The time series of annual values is presented for the selected TSL in chapter 14 of the direct final rule TSD.

TABLE V.37—PRESENT VALUE OF METHANE EMISSIONS REDUCTION FOR CONSUMER CLOTHES DRYERS SHIPPED IN 2027–2056 *

TSL	SC–CH_4 case discount rate and statistics			
	5% Average	3% Average	2.5% Average	3% 95th percentile
	(*million 2022$*)			
1	57	165	229	438
2	156	450	623	1,193
3	259	754	1,046	1,996
4	331	954	1,321	2,527
5	801	2,342	3,252	6,200
6	805	2,354	3,268	6,230

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

TABLE V.38—PRESENT VALUE OF NITROUS OXIDE EMISSIONS REDUCTION FOR CONSUMER CLOTHES DRYERS SHIPPED IN 2027–2056 *

TSL	SC–N_2O case discount rate and statistics			
	5% Average	3% Average	2.5% Average	3% 95th percentile
	(*million 2022$*)			
1	0.4	1.6	2.5	4.4
2	1.2	4.6	7.1	12.3
3	1.9	7.5	11.6	20.0
4	2.7	10.3	15.8	27.4
5	7.1	27.6	42.5	73.6
6	7.1	27.8	42.7	74.0

* The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the global and U.S. economy continues to evolve rapidly. DOE, together with other Federal agencies, will continue to review methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing

review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. DOE notes, however, that the adopted standards would be economically justified even without inclusion of monetized benefits of reduced GHG emissions.

DOE also estimated the monetary value of the economic benefits associated with NO_X and SO_2 emissions reductions anticipated to result from the considered TSLs for consumer clothes dryers. The dollar-per-ton values that DOE used are discussed in section IV.L.2 of this document. Table V.39 presents the present value for NO_X emissions reductions for each TSL calculated using 7-percent and 3-percent discount rates, and Table V.40 presents similar results for SO_2 emissions reductions. The results in these tables reflect application of EPA's low dollar-per-ton values, which DOE used to be conservative. The time series of annual values is presented for the selected TSL in chapter 14 of the direct final rule TSD.

TABLE V.39—PRESENT VALUE OF NO_X EMISSIONS REDUCTION FOR CONSUMER CLOTHES DRYERS SHIPPED IN 2027–2056 *

TSL	7% Discount rate	3% Discount rate
	million 2022$	
1	502	1,167
2	1,391	3,216
3	2,217	5,305
4	2,962	6,887
5	7,133	17,135
6	7,168	17,222

Note: Results are based on the low benefit-per-ton values.

*The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

TABLE V.40—PRESENT VALUE OF SO_2 EMISSIONS REDUCTION FOR CONSUMER CLOTHES DRYERS SHIPPED IN 2027–2056 *

TSL	7% Discount rate	3% Discount rate
	million 2022$	
1	93	209
2	265	594
3	415	963
4	590	1,333
5	1,541	3,630
6	1,550	3,651

*The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

Not all the public health and environmental benefits from the reduction of greenhouse gases, NO_X, and SO_2 are captured in the values above, and additional unquantified benefits from the reductions of those pollutants as well as from the reduction of direct particulate matter (''PM'') and other co-pollutants may be significant. DOE has not included monetary benefits of the reduction of Hg emissions because the amount of reduction is very small.

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) No other factors were considered in this analysis.

8. Summary of Economic Impacts

Table V.41 presents the NPV values that result from adding the estimates of the economic benefits resulting from reduced GHG and NO_X and SO_2 emissions to the NPV of consumer benefits calculated for each TSL considered in this rulemaking. The consumer benefits are domestic U.S. monetary savings that occur as a result of purchasing the covered products and are measured for the lifetime of products shipped during the period 2027–2056.[127] The climate benefits associated with reduced GHG emissions resulting from the adopted standards are global benefits and are also calculated based on the lifetime of consumer clothes dryers shipped during the period 2027–2056.[128]

TABLE V.41—CONSUMER NPV COMBINED WITH PRESENT VALUE OF CLIMATE BENEFITS AND HEALTH BENEFITS

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Using 3% discount rate for Consumer NPV and Health Benefits (billion 2022$)						
5% Average SC–GHG case	5.6	16.7	27.2	29.2	54.8	54.2
3% Average SC–GHG case	6.2	18.2	29.7	32.4	62.8	62.2
2.5% Average SC–GHG case	6.6	19.2	31.4	34.6	68.4	67.9
3% 95th percentile SC–GHG case	7.6	22.1	36.2	40.8	83.9	83.4
Using 7% discount rate for Consumer NPV and Health Benefits (billion 2022$)						
5% Average SC–GHG case	2.7	8.1	12.7	13.1	20.5	20.1
3% Average SC–GHG case	3.3	9.6	15.2	16.3	28.5	28.2
2.5% Average SC–GHG case	3.6	10.6	16.9	18.5	34.1	33.8
3% 95th percentile SC–GHG case	4.7	13.5	21.7	24.7	49.6	49.4

C. Conclusion

When considering new or amended energy conservation standards, the standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or

[127] The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

[128] *Id.*

amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

For this direct final rule, DOE considered the impacts of amended standards for consumer clothes dryers at each TSL, beginning with the maximum technologically feasible level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off upfront costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings as a result of (1) a lack of information; (2) a lack of sufficient salience of the long-term or aggregate benefits; (3) a lack of sufficient savings to warrant delaying or altering purchases; (4) excessive focus on the short-term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments; (5) computational or other difficulties associated with the evaluation of relevant tradeoffs; and (6) a divergence in incentives (for example, between renters and owners, or builders and purchasers). Having less-than-perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher-than-expected rate between current consumption and uncertain future energy cost savings.

It is important to recognize that while DOE is promulgating two separate regulatory actions for energy efficiency standards for residential clothes washers and consumer dryers, clothes washers and dryers are complementary products, and they are sometimes sold and purchased together as joint goods. This type of consumer purchasing behavior is not typical of DOE energy efficiency standards. These products are available in a variety of combinations and the efficiency and/or product class of one product does not restrict the efficiency and/or product class of the other. The efficiency levels are independent of each other. Hence, DOE does not directly model the joint purchasing decision of clothes washers and dryers in this rule. It is possible that if only one machine fails, consumers could replace one machine or could replace both machines jointly. If consumers replace both machines when one fails, aggregate lifecycle costs would be the combination of impacts as presented in both final rules.

Consumers value a variety of attributes in consumer clothes dryers. These attributes can factor into consumer purchasing decisions along with installation and operating cost. For example, DOE understands certain consumers make purchasing decisions on non-efficiency attributes such as color or other visual features such as control panel layout, which may overlap with efficiency considerations related to and a potential preference for mechanical over electronic controls.

One specific attribute related to the joint use of clothes washers and dryers worth noting is the moisture content of clothes as consumers wash and dry them. DOE recognizes that amended clothes washer standards could result in less total moisture needing to be removed from the clothing in a dryer, whereas amended clothes dryer standards could result in a less energy-intensive process for removing that moisture. As explained on page 99, the amended dryer test procedure in appendix D2 includes incoming RMC values (*i.e.,* a starting lower moisture content for the load) that are more representative of the resulting moisture content seen in high-efficiency clothes washers. Due to the uniqueness of the Joint Recommendation where the clothes washer and dryer proposals and compliance dates were aligned, the dryer rulemaking encompasses these lower initial moisture values as a starting point for the energy use analysis, so the effect of faster spin speeds resulting in less ''wet'' clothes is already captured by DOE. The relative comparison of efficiency levels for a given product would remain the same, even if the baseline energy consumption were adjusted due to an increase in efficiency in the complementary product.

General considerations for consumer welfare and preferences as well as the special cases of complementary goods are areas DOE plans to explore in a forthcoming RFI related to the agency's updates to its overall analytic framework.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forego the purchase of a product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the MIA. Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a standard decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the direct final rule TSD. However, DOE's current analysis does not explicitly control for heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or consumer price sensitivity variation according to household income.[129]

While DOE is not prepared at present to provide a fuller quantifiable framework for estimating the benefits and costs of changes in consumer purchase decisions due to an energy conservation standard, DOE is committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards. DOE has posted a paper that discusses the issue of consumer welfare impacts of appliance energy conservation standards, and potential enhancements to the methodology by which these impacts are defined and estimated in the regulatory process.[130]

1. Benefits and Burdens of TSLs Considered for Consumer Clothes Dryer Standards

Table V.42 and Table V.43 summarize the quantitative impacts estimated for each TSL for consumer clothes dryers. The national impacts are measured over the lifetime of consumer clothes dryers purchased in the 30-year period that begins in the anticipated year of

[129] P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies.* 2005. 72(3): pp. 853–883. doi: *10.1111/0034–6527.00354.*

[130] Sanstad, A. H. *Notes on the Economics of Household Energy Consumption and Technology Choice.* 2010. Lawrence Berkeley National Laboratory. Available at *www1.eere.energy.gov/buildings/appliance_standards/pdfs/consumer_ee_theory.pdf* (last accessed July 1, 2021).

compliance with amended standards (2027–2056).[131] The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle results. DOE is presenting monetized benefits of GHG emissions reductions in accordance with the applicable Executive orders and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the Interim Estimates presented by the Interagency Working Group. The efficiency levels contained in each TSL are described in section V.A of this document.

TABLE V.42—SUMMARY OF ANALYTICAL RESULTS FOR CONSUMER CLOTHES DRYERS TSLS: NATIONAL IMPACTS

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Cumulative FFC National Energy Savings (*quads*)						
Quads	0.57	1.58	2.66	3.52	9.70	9.76
Cumulative FFC Emissions Reduction (Total FFC Emissions)						
CO_2 (*million metric tons*)	12.4	34.1	57.1	73.5	188.6	189.6
CH_4 (*thousand tons*)	114.8	311.4	527.6	661.6	1,646	1,654
N_2O (*thousand tons*)	0.1	0.3	0.5	0.6	1.7	1.7
NO_X (*thousand tons*)	25.4	69.0	116.5	146.7	364.1	366.0
SO_2 (*thousand tons*)	3.0	8.4	13.9	19.0	53.3	53.6
Hg (*tons*)	0.02	0.1	0.1	0.1	0.4	0.4
Present Value of Monetized Benefits and Costs (*3% discount rate, billion 2022$*)						
Consumer Operating Cost Savings	4.3	12.7	21.1	28.8	77.4	77.8
Climate Benefits *	0.7	2.0	3.3	4.3	10.8	10.9
Health Benefits **	1.4	3.8	6.3	8.2	20.8	20.9
Total Benefits †	6.4	18.5	30.7	41.3	108.9	109.5
Consumer Incremental Product Costs ‡	0.2	0.4	1.0	8.9	46.2	47.3
Consumer Net Benefits	4.1	12.3	20.1	19.9	31.2	30.5
Total Net Benefits	6.2	18.2	29.7	32.4	62.8	62.2
Present Value of Monetized Benefits and Costs (*7% discount rate, billions 2022$*)						
Consumer Operating Cost Savings	2.0	6.1	9.8	13.7	35.2	35.4
Climate Benefits *	0.7	2.0	3.3	4.3	10.8	10.9
Health Benefits **	0.6	1.7	2.6	3.6	8.7	8.7
Total Benefits †	3.4	9.8	15.8	21.6	54.7	55.0
Consumer Incremental Product Costs ‡	0.1	0.2	0.6	5.3	26.2	26.8
Consumer Net Benefits	1.9	5.9	9.2	8.4	9.0	8.6
Total Net Benefits	3.3	9.6	15.2	16.3	28.5	28.2

Note: This table presents the costs and benefits associated with consumer clothes dryers shipped during the period 2027–2056 for all TSLs except TSL 3 (the Recommended TSL) and 2028–2057 for TSL 3. These results include benefits to consumers which accrue after 2056 from the products shipped during the period 2027–2056 for all TSLs except for TSL 3 and 2057 from the products shipped during the period 2028–2057.

* Climate benefits are calculated using four different estimates of the SC–CO_2, SC–CH_4 and SC–N_2O. Together, these represent the global SC–GHG. For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown; however, DOE emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for NO_X and SO_2) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. *See* section IV.L of this document for more details.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate.

TABLE V.43—SUMMARY OF ANALYTICAL RESULTS FOR CONSUMER CLOTHES DRYERS TSLS: MANUFACTURER AND CONSUMER IMPACTS

Category	TSL 1 *	TSL 2 *	TSL 3 *	TSL 4 *	TSL 5 *	TSL 6 *
Manufacturer Impacts						
Industry NPV (million 2022$) (No-new-standards case INPV = 2,115.4).	2,080.3–2,084.3.	2,061.1–2,069.5	1,971.2–1,995.8	1,501.9–1,724.8	679.9–1,800.8	604.3–1,753.5
Industry NPV (*% change*).	(1.7)–(1.5) ..	(2.6)–(2.2)	(6.8)–(5.7)	(29.0)–(18.5)	(67.9)–(14.9)	(71.4)–(17.1)

[131] The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

TABLE V.43—SUMMARY OF ANALYTICAL RESULTS FOR CONSUMER CLOTHES DRYERS TSLS: MANUFACTURER AND CONSUMER IMPACTS—Continued

Category	TSL 1 *	TSL 2 *	TSL 3 *	TSL 4 *	TSL 5 *	TSL 6 *
Consumer Average LCC Savings (2022$)						
Electric, Standard	150	170	252	101	41	41
Electric, Compact (120 V).	53	83	66	66	66	(209)
Vented Electric, Compact (240 V).	38	89	90	90	22	(230)
Vented Gas, Standard	48	112	102	102	13	13
Ventless Electric, Compact (240 V).	0	99	99	99	99	(102)
Ventless Electric, Combination Washer-Dryer.	0	10	11	10	10	(531)
Shipment-Weighted Average *.	131	159	224	100	36	29
Consumer Simple PBP (years)						
Electric, Standard	0.5	0.5	0.6	2.1	5.8	5.8
Electric, Compact (120 V).	1.5	1.5	2.2	2.2	2.2	18.1
Vented Electric, Compact (240 V).	2.1	1.5	2.0	2.0	6.6	20.4
Vented Gas, Standard	2.5	1.3	1.9	1.9	5.0	5.0
Ventless Electric, Compact (240 V).	0.0	0.4	0.4	0.4	0.4	11.4
Ventless Electric, Combination Washer-Dryer.	0.0	0.0	0.0	0.0	0.0	46.3
Shipment-Weighted Average *.	0.9	0.6	0.8	2.1	5.6	6.1
Percent of Consumers that Experience a Net Cost						
Electric, Standard	1.2	0.9	0.9	48.0	63.1	63.1
Electric, Compact (120 V).	4.8	5.1	21.4	21.7	21.7	90.9
Vented Electric, Compact (240 V).	5.7	4.6	12.4	12.6	60.7	92.8
Vented Gas, Standard	2.7	1.7	7.1	7.0	68.7	68.7
Ventless Electric, Compact (240 V).	0.0	0.0	0.0	0.0	0.0	58.6
Ventless Electric, Combination Washer-Dryer.	0.0	0.0	0.0	0.0	0.0	95.0
Shipment-Weighted Average *.	1.5	1.0	2.0	40.4	63.3	64.5

Parentheses indicate negative (−) values.
* Weighted by shares of each product class in total projected shipments in 2027 for all TSLs except TSL 3 and in 2028 for TSL 3.

DOE first considered TSL 6, which represents the max-tech efficiency level and includes the design parameters of the most efficient products available on the market or in working prototypes for all product classes. The max-tech design options include heat pump technology for electric consumer clothes dryers and inlet air preheat technology for gas consumer clothes dryers. DOE's shipments analysis estimates approximately 1 percent of annual consumer clothes dryer shipments currently meet this level. TSL 6 would save an estimated 9.76 quads of energy, an amount DOE considers significant. Under TSL 6, the NPV of consumer benefit would be $8.6 billion using a discount rate of 7 percent, and $30.5 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 6 are 189.6 Mt of CO_2, 53.6 thousand tons of SO_2, 366.0 thousand tons of NO_X, 0.4 ton of Hg, 1,654 thousand tons of CH_4, and 1.7 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 6 is $10.9 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 6 is $8.7 billion using a 7-percent discount rate and $20.9 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 6 is $28.2 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 6 is $62.2 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At TSL 6, the average LCC impact on affected consumers is a savings of $41 for electric standard, −$209 for electric compact (120V), −$230 for vented electric compact (240V), $13 for vented gas standard, −$102 for ventless

electric compact (240V), and −$531 for ventless electric combination washer-dryer. The simple PBP is 6 years for electric standard, 18 years for electric compact (120V), 20 years for vented electric compact (240V), 5 years for vented gas standard, 11 years for ventless electric compact (240V), and 46 years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost is 63 percent for electric standard, 91 percent for electric compact (120V), 93 percent for vented electric compact (240V), 69 percent for vented gas standard, 59 percent for ventless electric compact (240V), and 95 percent for ventless electric combination washer-dryer. Overall, across the product classes, the majority of consumers will experience a net LCC cost, especially for senior households. DOE estimated that more 72 percent of senior-only households will experience a net LCC cost at TSL 6.

At TSL 6, the projected change in INPV ranges from a decrease of $1,511.1 million to a decrease of $361.9 million, corresponding to decreases of 71.4 percent and 17.1 percent, respectively. The loss in INPV is largely driven by industry conversion costs as manufacturers work to redesign their portfolios of model offerings and retool entire factories to comply with amended standards at this level. Industry conversion costs could reach $1,516.9 million at this TSL.

Conversion costs at TSL 6 are significant, as nearly all existing consumer clothes dryer models would need to be redesigned to meet the max-tech efficiencies. Approximately 1 percent of industry shipments currently meet TSL 6. For the electric clothes dryer product classes, manufacturers would need to implement heat pump technology to meet max-tech levels. Out of the 19 OEMs that manufacture electric consumer clothes dryers, nine OEMs offer heat pump models for the U.S. market. The remaining 10 OEMs do not offer any models for the domestic market that utilize heat pump technology. A standard that could only be met using heat pump technology would require a total renovation of existing production facilities and would require most manufacturers to design completely new clothes dryer platforms, as they would not be able to maintain the resistive heating designs that currently dominate the U.S. electric clothes dryer market. In interviews, several manufacturers expressed concern about a potential shortage of products given the required scale of investment, redesign efforts, and 3-year compliance timeline.

For gas consumer clothes dryers, manufacturers would need to implement inlet air preheat technology along with other design options to meet the efficiency levels required by TSL 6. Thus far, consumer clothes dryers with this technology and performance have not been observed in consumer clothes dryers available on the consumer market. Consumer clothes dryers with inlet air preheat designs have been observed only in laboratory settings. In interviews, some manufacturers raised concerns about implementing a relatively untested technology for the consumer market. There is very little industry experience with inlet air preheat designs. Several manufacturers speculated that implementing inlet air preheat technology would require a major overhaul of existing production facilities and a significant amount of engineering time.

At this level, DOE estimates an 11-percent drop in shipments in the year the standard takes effect compared to the no-new-standards case, as price-sensitive consumers may forgo purchasing a new clothes dryer or rely on alternatives such as repair or purchasing a used dryer due to the increased upfront cost of baseline models.

The Secretary concludes that at TSL 6 for consumer clothes dryers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on many consumers, especially senior-only households, as well as the impacts on manufacturers, including the potential for large conversion costs and reduction in INPV.

TSL 6, representing the most efficient heat pump technology on the market, would provide significant energy savings potential, as discussed. Despite the current and potential future benefits of heat pump technology, the analysis at TSL 6 indicates that a significant fraction of consumers, including low-income and senior-only households, would experience a net cost given the current relatively high incremental cost of certain consumer clothes dryers at the max-tech efficiency level. This is particularly pronounced for electric standard clothes dryers, where the incremental production cost at the max-tech efficiency level is comparable to the manufacturer production cost for the baseline efficiency level. Consumers with existing electric standard clothes dryers below EL 4 (about 55 percent) and consumers with existing vented gas standard clothes dryers below EL 3 (about 50 percent) are more likely to experience a net cost at TSL 6, given the relatively modest decrease in operating costs compared to the high incremental installed costs as represented by the weighted average LCC savings of $30. Few products currently meet the efficiency levels required by TSL 6. DOE estimates that approximately 1 percent of current shipments meet the max-tech efficiencies. At max-tech, limited industry experience by certain manufacturers with the high-efficiency design options, the large conversion costs to update facilities and product designs, and expected drop in industry shipments would result in a reduction of INPV and a potential shortage of products given the required scale of investment, redesign efforts, and time constraints. Consequently, the Secretary has concluded that TSL 6 is not economically justified.

DOE then considered TSL 5, which represents the maximum energy savings with maximum positive NPV. TSL 5 corresponds to the max-tech level (EL 7), which represents heat pump technology, for the electric standard product class, and the efficiency levels corresponding to modulating (2-stage) heating technology in the electric compact (120V) and inlet air preheat technology in the vented electric compact (240V) product classes considered in this analysis. For the vented gas standard product class, TSL 5 corresponds to the max-tech level (EL 4), which represents inlet air preheat technology. TSL 5 would save an estimated 9.70 quads of energy, an amount DOE considers significant. Under TSL 5, the NPV of consumer benefit would be $9.0 billion using a discount rate of 7 percent, and $31.2 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 5 are 188.6 Mt of CO_2, 53.3 thousand tons of SO_2, 364.1 thousand tons of NO_X, 0.4 ton of Hg, 1,646 thousand tons of CH_4, and 1.7 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 5 is $10.8 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 5 is $ 8.7 billion using a 7-percent discount rate and $20.8 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 5 is $28.5 billion.

Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 5 is $62.8 billion. The estimated total NPV is provided for additional information, however DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At TSL 5, the average LCC impact on affected consumers is a savings of $41 for electric standard, $66 for electric compact (120V), $22 for vented electric compact (240V), $13 for vented gas standard, $99 for ventless electric compact (240V), and $10 for ventless electric combination washer-dryer. The simple PBP is 6 years for electric standard, 2 years for electric compact (120V), 7 years for vented electric compact (240V), 5 years for vented gas standard, 0.4 years for ventless electric compact (240V), and zero years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost is 63 percent for electric standard, 22 percent for electric compact (120V), 61 percent for vented electric compact (240V), 69 percent for vented gas standard, and zero percent for ventless electric compact (240V) and ventless electric combination washer-dryer. Overall, across the product classes, approximately 63 percent of consumers will experience a net LCC cost, especially for senior-only households. DOE estimated that more than 71 percent of senior-only households will experience a net LCC cost at TSL 5.

At TSL 5, the projected change in INPV ranges from a decrease of $1,435.5 million to a decrease of $314.6 million, corresponding to decreases of 67.9 percent and 14.9 percent, respectively. Industry conversion costs could reach $1,436.9 million at this TSL.

DOE's shipments analysis estimates approximately 2 percent of annual shipments currently meet this level. At TSL 5, the efficiency levels and analyzed design options for electric standard and vented gas standard dryers (which together account for approximately 98 percent of industry shipments) are the same as at max-tech. Thus, requiring heat pump technology for electric standard dryers and inlet air preheat for vented gas standard dryers would result in similar conversion costs, reduction in INPV, and drop in shipments as TSL 6.

At this level, DOE estimates a 11-percent drop in shipments in the year the standard takes effect compared to the no-new-standards case, as price-sensitive consumers may forgo purchasing a new clothes dryer or rely on alternatives such as repair or purchasing a used dryer due to the increased upfront cost of baseline models.

The Secretary concludes that at TSL 5 for consumer clothes dryers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on many consumers, especially senior-only households, as well as the impacts on manufacturers, including the significant conversion costs and large potential reduction in INPV. A significant fraction of electric standard clothes dryer consumers, including low-income and senior-only households, would experience a net cost. This is due to the high incremental cost of electric standard clothes dryers at the max-tech efficiency level. Consumers with existing electric standard clothes dryers below EL 4 are more likely to experience a net cost at TSL 5, given the relatively modest decrease in operating costs compared to the high incremental installed costs. DOE estimates that approximately 2 percent of shipments currently meet the efficiencies required by this TSL. At TSL 5, the limited industry experience by certain manufacturers with the high-efficiency design options, the large conversion costs to update facilities and product designs, and expected drop in industry shipments would result in a reduction of INPV and a potential shortage of products given the required scale of investment, redesign efforts, and time constraints. Consequently, the Secretary has concluded that TSL 5 is not economically justified.

DOE then considered TSL 4, which represents the maximum national energy savings with simple PBP less than 4 years for each product class. TSL 4 corresponds to the EL that represents inlet air preheat technology for the electric standard product class considered in this analysis. For the electric compact (120V) and vented electric compact (240V) product classes, TSL 4 corresponds to EL 4, which represents modulating (2-stage) heating technology. For the vented gas standard product class, TSL 4 corresponds to EL 3, which also represents modulating (2-stage) heating technology. TSL 4 would save an estimated 3.52 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be $8.4 billion using a discount rate of 7 percent, and $19.9 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 are 73.5 Mt of CO_2, 19.0 thousand tons of SO_2, 146.7 thousand tons of NO_X, 0.1 ton of Hg, 661.6 thousand tons of CH_4, and 0.6 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 4 is $4.3 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 4 is $3.6 billion using a 7-percent discount rate and $8.2 million using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 4 is $16.3 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 4 is $32.4 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At TSL 4, the average LCC impact on affected consumers is a savings of $101 for electric standard, $66 for electric compact (120V), $90 for vented electric compact (240V), $102 for vented gas standard, $99 for ventless electric compact, and $10 for ventless electric combination washer-dryer. The simple PBP is 2 years for electric standard, 2 years for electric compact (120V), 2 years for vented electric compact (240V), 2 years for vented gas standard, 0.4 years for ventless electric compact (240V), and 0 years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost is 48 percent for electric standard, 22 percent for electric compact (120V), 13 percent for vented electric compact (240V), 7 percent for vented gas standard, and zero percent for ventless electric compact (240V) and ventless electric combination washer-dryer. Overall, across the product classes, approximately 40 percent of consumers will experience a net LCC cost, especially for senior households. DOE estimated that about 45 percent of senior-only households will experience a net LCC cost at TSL 4.

At TSL 4, the projected change in INPV ranges from a decrease of $613.5 million to a decrease of $390.6 million, corresponding to decreases of 29.0 percent and 18.5 percent, respectively. Industry conversion costs could reach $667.5 million at this TSL.

At TSL 4, the majority of consumer clothes dryer models would need to be redesigned to meet the efficiency levels required. DOE's shipments analysis

estimates approximately 15 percent of current shipments meet this level. For electric standard dryers, the design options include implementing inlet air preheat and other features. As previously noted, electric standard dryers account for approximately 81 percent of total shipments. At the current time, there is very little industry experience with inlet air preheat designs. Currently, DOE is not aware of any consumer clothes dryers on the market utilizing this design option. DOE's shipments analysis estimates that approximately 7 percent of electric standard shipments currently meet the efficiency required by TSL 4. Implementing inlet air preheat for electric standard dryers would represent a major overhaul of existing product lines and manufacturing facilities. This change would necessitate significant investments in new equipment and tooling. Product conversion costs would be necessary for designing, prototyping, and testing new or updated platforms.

For vented gas standard clothes dryers, the analyzed design option at TSL 4 includes modulating (2-stage) heat technology, among other design options. Out of the nine OEMs that manufacture vented gas standard clothes dryers, eight offer products that meet the efficiencies required at TSL 4. DOE does not believe that there are any substantive barriers to modulating (2-stage) heating technology. Capital conversion costs would be necessary as manufacturers increase tooling for 2-stage heating systems. Product conversion costs would be necessary for cost-optimizing and testing new designs for a market with amended standards.

At this level, DOE does not expect a notable drop in shipments in the year the standard takes effect.

The Secretary concludes that at TSL 4 for consumer clothes dryers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on many consumers, especially senior-only households, as well as the impacts on manufacturers, including the conversion costs and profit margin impacts that could result in a large reduction in INPV. A significant fraction of electric standard clothes dryer consumers, including senior-only households, would experience a net cost. This is due to the high incremental cost of electric standard clothes dryers at the inlet air preheat technology efficiency level. Consumers with existing electric standard clothes dryers below EL 4 are more likely to experience a net cost at TSL 4, given the relatively modest decrease in operating costs compared to the high incremental installed costs. For electric standard dryers, DOE estimates that approximately 7 percent of shipments currently meet the efficiency level required by this TSL. At TSL 4, the limited industry experience of electric standard dryer manufacturers with inlet air preheat technology and the large conversion costs to update facilities and product designs, would result in a large reduction of INPV. Consequently, the Secretary has concluded that TSL 4 is not economically justified.

DOE then considered the Recommended TSL, which represents a set of intermediate efficiency levels between those designated in TSL 2 and TSL 4 and corresponds to the current ENERGY STAR efficiency levels for the electric standard and vented gas standard product classes, which represent approximately 98 percent of the market. The Recommended TSL corresponds to the EL that represents modulating (2-stage) heating technology for the electric standard and electric compact (120V) product classes. For the vented gas standard product class, the Recommended TSL corresponds to EL 3, which also represents modulating (2-stage) heating technology. For the vented gas compact product class, the Recommended TSL corresponds to baseline CEF_{D2}. For the electric compact (240V) product classes, the Recommended TSL corresponds to EL 2 for vented consumer clothes dryers, which represents a model with an optimized heating system and EL 1 for ventless consumer clothes dryers, which represents a baseline model with a more advanced automatic termination control system. For the ventless electric combination washer-dryer product class, the Recommended TSL corresponds to EL 1, which represents a baseline model with high-speed spin technology. The Recommended TSL would save an estimated 2.66 quads of energy, an amount DOE considers significant. Under the Recommended TSL, the NPV of consumer benefit would be $9.23 billion using a discount rate of 7 percent, and $20.08 billion using a discount rate of 3 percent.

The cumulative emissions reductions at the Recommended TSL are 57.1 Mt of CO_2, 13.9 thousand tons of SO_2, 116.5 thousand tons of NO_X, 0.1 ton of Hg, 527.6 thousand tons of CH_4, and 0.5 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 3 is $3.3 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 3 is $2.6 billion using a 7-percent discount rate and $6.3 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at the Recommended TSL is $15.2 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at the Recommended TSL is $29.7 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At the Recommended TSL, the average LCC impact on affected consumers is a savings of $252 for electric standard, $66 for electric compact (120V), $90 for vented electric compact (240V), $102 for vented gas standard, $99 for ventless electric compact, and $11 for ventless electric combination washer-dryer. The simple PBP is 1 year for the largest product class (electric standard), 2 years for electric compact (120V), 2 years for vented electric compact (240V), 2 years for vented gas standard, 0.4 years for ventless electric compact (240V), and 0 years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost is 1 percent for electric standard, 21 percent for PC 2, 12 percent for vented electric compact (240V), 7 percent for vented gas standard, and zero percent for ventless electric compact (240V) and ventless electric combination washer-dryer. Overall, across the product classes, approximately 2 percent of consumers, including low-income and senior-only households, will experience a net LCC cost.

At the Recommended TSL, the projected change in INPV ranges from a decrease of $144.2 million to a decrease of $119.7 million, corresponding to decreases of 6.8 percent and 5.7 percent, respectively. Industry conversion costs could reach $180.7 million at this TSL.

DOE expects that some existing consumer clothes dryer models would need to be redesigned to meet the Recommended TSL efficiencies, but there are a wide range of available models for vented electric standard dryers due to participation in the ENERGY STAR program. DOE's shipments analysis estimates approximately 48 percent of annual shipments currently meet this level. For electric standard, electric compact

(120V), vented electric compact (240V), and vented gas standard clothes dryers, which account for approximately 99 percent of total annual shipments, the design options include implementing electronic controls, optimized heating systems, more advanced automatic termination controls, and modulating (2-stage) heat. Of the 19 electric dryer OEMs, 14 offer products at or above the efficiencies required for the electric dryer product classes at the Recommended TSL. Out of the nine OEMs that manufacture vented gas standard clothes dryers, eight offer products that meet the efficiencies required at the Recommended TSL. Capital conversion costs may be necessary as manufacturers increase tooling for 2-stage heating systems. Manufacturers may choose to further cost-optimize and test new designs as a result of the standards, but DOE believes some of this has already occurred in response to ENERGY STAR. DOE does not expect any drop in shipments in the year the standard takes effect.

For all TSLs considered in this direct final rule—except for the Recommended TSL—DOE is bound by the 3-year lead time requirements in EPCA when determining compliance dates (*i.e.,* compliance with amended standards required in 2027). For the Recommended TSL, DOE's analysis utilized the March 1, 2028, compliance date specified in the Joint Agreement as it was an integral part of the multi-product joint recommendation. A 2028 compliance year provides manufacturers additional flexibility to spread capital requirements, engineering resources, and conversion activities over a longer period of time depending on the individual needs of each manufacturer.

At the Recommended TSL, DOE's data demonstrate no negative impact on consumer utility for consumer clothes dryers. In addition, the second joint statement from the same group of stakeholders that submitted the Joint Agreement states that DOE's test data show, and industry experience agrees, that the recommended standard level for consumer clothes dryers will not result in significant differences in cycle time and will adequately dry clothes.[132] Based on the information available, DOE concludes that no lessening of product utility or performance would occur at the Recommended TSL.

After considering the analysis and weighing the benefits and burdens, the Secretary has concluded that a standard set at the Recommended TSL for consumer clothes dryers would result in the maximum improvement in energy efficiency that is technologically feasible and economically justified and also result in the significant conservation of energy. At this TSL, the average LCC savings for all consumer clothes dryer product classes are positive. An estimated weighted average of 2 percent of consumer clothes dryer consumers would experience a net cost. The FFC national energy savings are significant and the NPV of consumer benefits is positive using both a 3-percent and 7-percent discount rate. Notably, the benefits to consumers vastly outweigh the cost to manufacturers. At the Recommended TSL, the NPV of consumer benefits, even measured at the more conservative discount rate of 7 percent, is over 64 times higher than the maximum estimated manufacturers' loss in INPV. The positive LCC savings—a different way of quantifying consumer benefits—reinforces this conclusion. The standard levels at the Recommended TSL are economically justified even without weighing the estimated monetary value of emissions reductions. When those emissions reductions are included—representing $3.3 billion in climate benefits (associated with the average SC–GHG at a 3-percent discount rate), and $6.3 billion (using a 3-percent discount rate) or $2.6 billion (using a 7-percent discount rate) in health benefits—the rationale becomes stronger still.

As stated, DOE conducts the walk-down analysis to determine the TSL that represents the maximum improvement in energy efficiency that is technologically feasible and economically justified as required under EPCA. The walk-down is not a comparative analysis, as a comparative analysis would result in the maximization of net benefits instead of energy savings that are technologically feasible and economically justified, which would be contrary to the statute. 86 FR 70892, 70908. Although DOE has not conducted a comparative analysis to select the amended energy conservation standards, DOE notes that as compared to TSL 6, TSL 5, and TSL 4, the Recommended TSL has higher average LCC savings, smaller percentages of consumers experiencing a net cost, a lower maximum decrease in INPV, and lower manufacturer conversion costs.

Although DOE considered amended standard levels for consumer clothes dryers by grouping the efficiency levels for each product class into TSLs, DOE evaluates all analyzed efficiency levels in its analysis. Accordingly, the Secretary has concluded that the Recommended TSL would offer the maximum improvement in efficiency that is technologically feasible and economically justified and would result in the significant conservation of energy. For electric standard and vented gas standard consumer clothes dryers, which account for approximately 98 percent of U.S. shipments, requiring efficiency levels above the levels required by the Recommended TSL result in a large percentage of consumers experiencing a net LCC cost, in addition to significant manufacturer impacts and reductions in INPV. Additionally, for consumer clothes dryers, most manufacturers offer products that can meet the Recommended TSL across both electric and gas consumer clothes dryers. In addition, the Recommended TSL corresponds to the current ENERGY STAR levels for electric standard and vented gas standard clothes dryers, which have significant market share and manufacturer support due to their promotion over the past couple of years as a voluntary energy efficiency program. The adoption of standards, if finalized, at this TSL may encourage ENERGY STAR to further consider more efficient levels for dryers in the year leadings up to the compliance of date of the standard, which would in turn likely spur additional market introductions of consumer clothes dryers with heat pump technology, foster maturation of the technology and downward price trends, and further support differentiation within the dryer market for energy efficient products. For electric and vented gas standard consumer clothes dryers, the Recommended TSL is comprised of EL 4 and EL 3, respectively, resulting in higher LCC savings, a significant reduction in the number of consumers experiencing a net cost, a lower maximum decrease in INPV, and lower conversion costs to the point where DOE has concluded they are economically justified, as discussed for the Recommended TSL in the preceding paragraphs.

Therefore, based on the previous considerations, DOE adopts the energy conservation standards for consumer clothes dryers at the Recommended TSL.

While DOE considered each potential TSL under the criteria laid out in 42 U.S.C. 6295(o) as discussed above, DOE notes that the Recommended TSL for consumer clothes dryers adopted in this direct final rule is part of a multi-product Joint Agreement covering six rulemakings (residential clothes washers; consumer clothes dryers;

[132] This document is available in the docket at: *www.regulations.gov/comment/EERE–2014–BT–STD–0058–0058.*

consumer conventional cooking products; dishwashers; refrigerators, refrigerator-freezers, and freezers; and miscellaneous refrigeration products). The signatories indicated that the Joint Agreement for the six rulemakings should be considered as a joint statement of recommended standards, to be adopted in its entirety. As discussed in section V.B.2.e of this document, many consumer clothes dryer OEMs also manufacture residential clothes dryers; consumer conventional cooking products; dishwashers; refrigerators, refrigerator-freezers, and freezers; and miscellaneous refrigeration products. Therefore, there are potential integrated benefits to the Joint Agreement. Rather than requiring compliance with five amended standards in a single year (2027),[133] the negotiated multi-product Joint Agreement staggers the compliance dates for the five amended standards over a 4-year period (2027–2030). In response to the August 2022 NOPR, AHAM expressed concerns about the timing of ongoing home appliance rulemakings. Specifically, AHAM commented that there are a number of ongoing regulations that impact consumer clothes dryer manufacturers. (AHAM, No. 46 at p. 13) AHAM has submitted similar comments to other ongoing home appliance rulemakings.[134] As AHAM is a key signatory of the Joint Agreement, DOE understands that the compliance dates recommended in the Joint Agreement would help reduce cumulative regulatory burden. These compliance dates help relieve concern on the part of some manufacturers about their ability to allocate sufficient resources to comply with multiple concurrent amended standards and about the need to align compliance dates for products that are typically designed or sold as matched pairs. The Joint Agreement also provides additional years of regulatory certainty for manufacturers and their suppliers.

For residential clothes washers and consumer clothes dryers specifically, aligned compliance dates would help reduce cumulative regulatory burden for the 13 OEMs that manufacture both residential clothes washers and consumer clothes dryers. In response to the August 2022 NOPR, AHAM commented that laundry products (RCWs and consumer clothes dryers) are designed and used in pairs. (AHAM, No. 46 at p. 10) AHAM stated that an additional design cycle for clothes washers and/or clothes dryers may be necessary if the effective compliance dates for the two products were out of sync. AHAM further stated that coordinated compliance dates would greatly reduce burden on manufacturers and retailers. (*Id.*)

The amended energy conservation standards for consumer clothes dryers, which are expressed as CEF_{D2}, are shown in Table V.44.

TABLE V.44—AMENDED ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

Product class	CEF_{D2} (lb/kWh)
(i) Electric, Standard (4.4 ft^3 or greater capacity)	*3.93*
(ii) Electric, Compact (120V) (less than 4.4 ft^3 capacity)	*4.33*
(iii) Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	*3.57*
(iv) Ventless Electric, Combination Washer-Dryer	*2.33*
(v) Vented Gas, Standard (4.4 ft^3 or greater capacity)	*3.48*
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	*2.68*
(vii) Vented Gas, Compact (less than 4.4 ft^3 capacity)	*2.02*

NEEA, the Joint Commenters, and Samsung supported DOE's proposed TSL 3, which aligns with the Recommended TSL in this direct final rule, given the national energy savings, life-cycle cost savings, and reasonable manufacturer impacts. According to the Joint Commenters, TSL 3 provides large cost savings for all consumer groups, including low-income households. Samsung supported DOE's proposed TSL 3 and believes the test sample adequately represents the current marketplace. (NEEA, No. 45 at p. 2; Joint Commenters, No. 51 at p. 2; Samsung, No. 54 at p. 2)

NYSERDA also supported DOE's proposal in the August 2022 NOPR and urged expedient adoption of the amended standards given significant LCC savings, reasonable payback periods, significant GHG emissions reductions, energy savings, and monetary benefits for consumers in New York and beyond, and the aging out of a significant portion of the installed dryer stock in New York. According to the 2019 New York Residential Building Stock Assessment, 49 percent of New York consumer clothes dryers are over 10 years old, and another 81 percent are 5 years or older. NYSERDA stated that based on DOE's assumption of a product lifetime average of 14 years, a significant number of dryers in New York will be due for replacement around the time of the new standard, but only if DOE finalizes this standard promptly. (NYSERDA, No. 48 at pp. 1–2)

While the California IOUs supported DOE's conclusion that TSL 3 represented an economically justified and technologically feasible efficiency level achieving significant energy savings, the California IOUs requested that DOE clarify the supporting data that led to the conclusion that TSL 4 was not economically justified. The California IOUs urged DOE to adopt TSL 3 at the earliest opportunity so that consumers may obtain the significant savings provided from this level. (California IOUs, No. 50 at pp. 1–2)

As previously stated, TSL 4 is not economically justified. Nearly 50 percent of electric standard clothes dryer users, including over 53 percent of senior-only households, would experience a net cost. This can be

[133] The analyses for residential clothes washers (88 FR 13520); consumer clothes dryers (87 FR 51734); consumer conventional cooking products (88 FR 6818); dishwashers (88 FR 32514); and refrigerators, refrigerator-freezers, and freezers (88 FR 12452) utilized a 2027 compliance year for analysis at the proposed rule stage. Miscellaneous refrigeration products (88 FR 12452) utilized a 2029 compliance year for the NOPR analysis.

[134] AHAM has submitted written comments regarding cumulative regulatory burden for the other five rulemakings included in the multi-product Joint Agreement. AHAM's written comments on cumulative regulatory burden are available at: *www.regulations.gov/comment/EERE-2017-BT-STD-0014-0464* (pp. 41–44) for residential clothes washers; *www.regulations.gov/comment/EERE-2014-BT-STD-0005-2285* (pp. 44–47) for consumer conventional cooking products; *www.regulations.gov/comment/EERE-2019-BT-STD-0039-0051* (pp. 21-24) for dishwashers; *www.regulations.gov/comment/EERE-2017-BT-STD-0003-0069* (pp. 20–22) for refrigerators, refrigerator-freezers, and freezers; and *www.regulations.gov/comment/EERE-2020-BT-STD-0039-0031* (pp. 12–15) for miscellaneous refrigeration products.

attributed to the high incremental cost of electric standard dryers with the inlet air preheat technology efficiency level. Moreover, the industry conversion costs for implementing TSL 4 could amount to $668 million, resulting in a substantial decrease in the manufacturer's INPV. In addition, there is very little industry experience with inlet air preheat designs. Currently, DOE is not aware of any consumer clothes dryers on the market utilizing this design option. DOE's shipments analysis estimates that approximately 7 percent of electric standard shipments currently meet the efficiency required by TSL 4. Implementing inlet air preheat for electric standard dryers would represent a major overhaul of existing product lines and manufacturing facilities.

2. Annualized Benefits and Costs of the Adopted Standards

The benefits and costs of the adopted standards can also be expressed in terms of annualized values. The annualized net benefit is (1) the annualized national economic value (expressed in 2022$) of the benefits from operating products that meet the adopted standards (consisting primarily of operating cost savings from using less energy), minus increases in product purchase costs, and (2) the annualized monetary value of the climate and health benefits.

Table V.45 shows the annualized values for consumer clothes dryers under the Recommended TSL, expressed in 2022$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and NO_X and SO_2 reductions, and the 3-percent discount rate case for GHG social costs, the estimated cost of the adopted standards for consumer clothes dryers is $60.0 million per year in increased equipment installed costs, while the estimated annual benefits are $971.4 million from reduced equipment operating costs, $185.5 million in GHG reductions, and $259.9 million from reduced NO_X and SO_2 emissions. In this case, the net benefit amounts to $1,357 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the adopted standards for consumer clothes dryers is $57.2 million per year in increased equipment costs, while the estimated annual benefits are $1,177 million in reduced operating costs, $185.5 million from GHG reductions, and $349.4 million from reduced NO_X and SO_2 emissions. In this case, the net benefit amounts to $1,654 million per year.

TABLE—V.45 ANNUALIZED MONETIZED BENEFITS AND COSTS OF ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS (THE RECOMMENDED TSL)

	Million 2022$/year		
	Primary Estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	1,177	1,103	1,230
Climate Benefits*	185.5	178.9	187.8
Health Benefits**	349.4	337.2	353.7
Total Benefits†	1,712	1,619	1,771
Consumer Incremental Product Costs‡	57.2	58.9	54.4
Net Benefits	1,654	1,560	1,717
Change in Producer Cashflow (INPV‡‡)	(12)–(10)	(12)–(10)	(12)–(10)
7% discount rate			
Consumer Operating Cost Savings	971.4	915.5	1,014
Climate Benefits*	185.5	178.9	187.8
Health Benefits**	259.9	251.5	262.8
Total Benefits†	1,417	1,346	1,464
Consumer Incremental Product Costs‡	60.0	61.2	57.7
Net Benefits	1,357	1,285	1,407
Change in Producer Cashflow (INPV‡‡)	(12)–(10)	(12)–(10)	(12)–(10)

Note: This table presents the costs and benefits associated with consumer clothes dryers shipped in 2028–2057. These results include benefits to consumers which accrue after 2057 from the products shipped in 2028–2057. The Primary, Low-Net-Benefits, and High-Net-Benefits estimates utilize projections of energy prices from the *AEO2023* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a constant rate in the Low-Net-Benefits Estimate, and a high decline rate in the High-Net-Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.H.3 of this document. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC–GHG (*see* section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. *See* section IV.L of this document for more details.

† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate.

‡ Costs include incremental equipment costs as well as installation costs.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's NIA includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (the MIA). *See* section IV.J of this document and chapter 12 of the direct final rule TSD. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 7.5 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the direct final rule TSD for a complete description of the industry weighted average cost of capital). For consumer clothes dryers, those values are −$12 million to −$10 million. DOE accounts for that range of likely impacts in analyzing whether a TSL is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two manufacturer markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table, and the Preservation of Operating Profit scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in chapter 12 of the direct final rule TSD, to provide additional context for assessing the estimated impacts of this direct final rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this direct final rule, the annualized net benefits, using the primary estimate, would range from $1,642 million to $,1644 million at 3-percent discount rate and would range from $1,345 million to $1,347 million at 7-percent discount rate. Parentheses ( ) indicate negative values.

VI. Procedural Issues and Regulatory Review

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,'' 76 FR 3821 (Jan. 21, 2011) 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 fees 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 (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this final regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to OIRA for review. OIRA has determined that this final regulatory action constitutes a ''significant regulatory action'' within the scope of section 3(f) of E.O. 12866. DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the final regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments are summarized in this preamble and further detail can be found in the technical support document for this rulemaking.

B. 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 (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') 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 E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 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 the General Counsel's website (*www.energy.gov/gc/office-general-counsel).*

DOE is not obligated to prepare a regulatory flexibility analysis for this rulemaking because there is not a requirement to publish a general notice of proposed rulemaking under the Administrative Procedure Act. See 5 U.S.C. 601(2), 603(a). As discussed previously, DOE has determined that the Joint Agreement meets the necessary requirements under EPCA to issue this direct final rule for energy conservation standards for consumer clothes dryers under the procedures in 42 U.S.C. 6295(p)(4). DOE notes that the NOPR for energy conservation standards for consumer clothes dryers published elsewhere in this issue of the **Federal Register** contains a regulatory flexibility analysis.

C. Review Under the Paperwork Reduction Act

Manufacturers of consumer clothes dryers must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for consumer clothes dryers, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including consumer clothes dryers. (*See generally* 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been

approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the 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 PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act of 1969 (''NEPA''), DOE has analyzed this rule in accordance with NEPA and DOE's NEPA implementing regulations (10 CFR part 1021). DOE has determined that this rule qualifies for categorical exclusion under 10 CFR part 1021, subpart D, appendix B5.1 because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, none of the exceptions identified in B5.1(b) apply, no extraordinary circumstances exist that require further environmental analysis, and it meets the requirements for application of a categorical exclusion. *See* 10 CFR 1021.410. Therefore, DOE has determined that promulgation of this rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA, and does not require an environmental assessment or an environmental impact statement.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable 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 this rule and has determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this direct final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 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 Attorney General. Section 3(c) of E.O. 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 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 direct final rule meets the relevant standards of E.O. 12988.

G. 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 *www.energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.*

DOE has concluded that this direct final rule may require expenditures of $100 million or more in any one year by the private sector. Such expenditures may include (1) investment in research and development and in capital expenditures by consumer clothes dryer manufacturers in the years between the direct final rule and the compliance date for the new standards and (2) incremental additional expenditures by consumers to purchase higher efficiency consumer clothes dryers starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a Federal agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the direct final rule. (2 U.S.C. 1532(c)) The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. This **SUPPLEMENTARY INFORMATION** section and the TSD for this direct final rule respond to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. (2 U.S.C. 1535(a)) DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives

of the rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(m), this direct final rule establishes amended energy conservation standards for consumer clothes dryers that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified, as required by 6295(o)(2)(A) and 6295(o)(3)(B). A full discussion of the alternatives considered by DOE is presented in chapter 17 of the TSD for this direct final rule.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Although this direct final rule would not have any impact on the autonomy or integrity of the family as an institution as defined, this rule could impact a family's well-being. When developing a Family Policymaking Assessment, agencies must assess whether: (1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and whether (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

DOE has considered how the proposed benefits of this rule compare to the possible financial impact on a family (the only factor listed that is relevant to this final rule). As part of its rulemaking process, DOE must determine whether the energy conservation standards contained in this direct final rule are economically justified. As discussed in section V.C.1 of this document, DOE has determined that the standards are economically justified because the benefits to consumers far outweigh the costs to manufacturers. Families will also see LCC savings as a result of this final rule. Moreover, as discussed further in section IV.I of this document, DOE's analysis estimated that 45 percent of low-income households who have a consumer clothes dryer would experience a net benefit and 54 percent of low-income households who have a consumer clothes dryer would have no impact under the adopted standards. Further, the standards will also result in climate and health benefits for families.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this direct final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 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 at OMB, a Statement of Energy Effects for any 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; and (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 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.

DOE has concluded that this regulatory action, which sets forth amended energy conservation standards for consumer clothes dryers, is not a significant energy action because the standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this direct final rule.

L. Information Quality

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (''OSTP''), issued its Final Information Quality Bulletin for Peer Review (''the Bulletin''). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2664, 2667.

In response to OMB's Bulletin, DOE conducted formal peer reviews of the energy conservation standards development process and the analyses that are typically used and prepared a report describing that peer review.[135] Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity

[135] The 2007 Energy Conservation Standards Rulemaking Peer Review Report is available at *energy.gov/eere/buildings/downloads/energy-conservation-standards-rulemaking-peer-review-report-0* (last accessed November 2021).

and management effectiveness of programs and/or projects. Because available data, models, and technological understanding have changed since 2007, DOE has engaged with the National Academy of Sciences to review DOE's analytical methodologies to ascertain whether modifications are needed to improve DOE's analyses. DOE is in the process of evaluating the resulting report.[136]

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that the Office of Information and Regulatory Affairs has determined that this action meets the criteria set forth in 5 U.S.C. 804(2).

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this direct final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

Signing Authority

This document of the Department of Energy was signed on February 29, 2024, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with 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 March 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons set forth in the preamble, DOE amends part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Amend § 430.32 by adding paragraph (h)(4) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(h) * * *

(4) Clothes dryers manufactured on or after March 1, 2028, shall have a combined energy factor, determined in accordance with appendix D2 of this subpart, no less than:

Product class	CEF_{D2} (lb/kWh)
(i) Electric, Standard (4.4 ft^3 or greater capacity) *	3.93
(ii) Electric, Compact (120V) (less than 4.4 ft^3 capacity)	4.33
(iii) Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	3.57
(iv) Vented Gas, Standard (4.4 ft^3 or greater capacity) **	3.48
(v) Vented Gas, Compact (less than 4.4 ft^3 capacity)	2.02
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	2.68
(vii) Ventless Electric, Combination Washer-Dryer	2.33

* The energy conservation standards in this product class do not apply to Vented Electric, Standard clothes dryers with a cycle time of less than 30 minutes, when tested according to appendix D2 in subpart B of this part.

** The energy conservation standards in this product class do not apply to Vented Gas, Standard clothes dryers with a cycle time of less than 30 minutes, when tested according to appendix D2 in subpart B of this part.

* * * * *

[FR Doc. 2024–04765 Filed 3–11–24; 8:45 am]

BILLING CODE 6450–01–P

[136] The report is available at *www.nationalacademies.org/our-work/review-of-methods-for-setting-building-and-equipment-performance-standards.*

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2014–BT–STD–0058]

RIN 1904–AF59

Energy Conservation Program: Energy Conservation Standards for Consumer Clothes Dryers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Energy Policy and Conservation Act, as amended (''EPCA''), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including consumer clothes dryers. In this notice of proposed rulemaking (''NOPR''), the U.S. Department of Energy (''DOE'') proposes amended energy conservation standards for consumer clothes dryers identical to those set forth in a direct final rule published elsewhere in this issue of the **Federal Register**. If DOE receives adverse comment and determines that such comment may provide a reasonable basis for withdrawal of the direct final rule, DOE will publish a notice of withdrawal rule and will proceed with this proposed rule.

DATES: DOE will accept comments, data, and information regarding this NOPR no later than July 1, 2024. Comments regarding the likely competitive impact of the proposed standard should be sent to the Department of Justice contact listed in the **ADDRESSES** section on or before April 11, 2024.

ADDRESSES: See section VII, ''Public Participation,'' for details. If DOE withdraws the direct final rule published elsewhere in this issue of the **Federal Register**, DOE will hold a public meeting to allow for additional comment on this proposed rule. DOE will publish notice of any meeting in the **Federal Register**.

Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2014–BT–STD–0058. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2014–BT–STD–0058, by any of the following methods:

(1) *Email: ApplicanceStandardsQuestions@ee.doe.gov.* Include the docket number EERE–2014–BT–STD–0058 in the subject line of the message.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section VII of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE–2014–BT–STD–0058.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section VII of this document for information on how to submit comments through *www.regulations.gov.*

EPCA requires the Attorney General to provide DOE a written determination of whether the proposed standard is likely to lessen competition. The U.S. Department of Justice Antitrust Division invites input from market participants and other interested persons with views on the likely competitive impact of the proposed standard. Interested persons may contact the Antitrust Division at *energy.standards@usdoj.gov* on or before the date specified in the **DATES** section. Please indicate in the ''Subject'' line of your email the title and Docket Number of this proposed rulemaking.

FOR FURTHER INFORMATION CONTACT:

Dr. Carl Shapiro, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–5649. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Matthew Schneider, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 597–6265. Email: *matthew.schneider@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Synopsis of the Proposed Rule

The Energy Policy and Conservation Act, Public Law 94–163, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B of EPCA [2] established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include consumer clothes dryers, the subject of this proposed rulemaking.

Pursuant to EPCA, any new or amended energy conservation standard must, among other things, be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C.

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

6295(o)(2)(A)) Furthermore, the new or amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

In light of the above and under the authority provided by 42 U.S.C. 6295(p)(4)(i), DOE is proposing this rule establishing and amending the energy conservation standards for consumer clothes dryers and is concurrently issuing a direct final rule published elsewhere in this issue of the **Federal Register**. DOE will proceed with this notice of proposed rulemaking (''NOPR'') only if it determines it must withdraw the direct final rule pursuant to the criteria provided in 42 U.S.C. 6295(p)(4). The amended standard levels in this proposed rule and the direct final rule were proposed in a letter submitted to DOE jointly by groups representing manufacturers, energy and environmental advocates, consumer groups, and a utility. This letter, titled ''Energy Efficiency Agreement of 2023'' (hereafter, the ''Joint Agreement'',[3]) recommends specific energy conservation standards for consumer clothes dryers. DOE subsequently received letters of support for the Joint Agreement from States including New York, California, and Massachusetts [4] and utilities including San Diego Gas and Electric and Southern California Edison [5] advocating for the adoption of the recommended standards. As discussed in more detail in the accompanying direct final rule and in accordance with the provisions at 42 U.S.C. 6295(p)(4), DOE has determined that the recommendations contained in the Joint Agreement comply with the requirements of 42 U.S.C. 6295(o).

In accordance with these and other statutory provisions discussed in this document, DOE proposes amended energy conservation standards for consumer clothes dryers. The standards are expressed in terms of the combined energy factor (''CEF_{D2}''), measured in pounds per kilowatt-hour (''lb/kWh''), as determined in accordance with DOE's consumer clothes dryer test procedure at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix D2 (''appendix D2''). The CEF metric includes active mode, standby mode, and off mode energy use.

Table I.1 presents the proposed standards for consumer clothes dryers. The proposed standards are the same as those recommended by the Joint Agreement. These standards would apply to all products listed in Table I.1 and manufactured in, or imported into, the United States starting on March 1, 2028, as recommended in the Joint Agreement.

TABLE I.1—PROPOSED ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

[Compliance starting March 1, 2028]

Product class	Minimum CEF_{D2} (lb/kWh)
(i) Electric, Standard (4.4 cubic feet (''ft3'') or greater capacity)	3.93
(ii) Electric, Compact (120 volts (''V'')) (less than 4.4 ft3 capacity)	4.33
(iii) Vented Electric, Compact (240V) (less than 4.4 ft3 capacity)	3.57
(iv) Vented Gas, Standard (4.4 ft3 or greater capacity)	3.48
(v) Vented Gas, Compact (less than 4.4 ft3 capacity)	2.02
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft3 capacity)	2.68
(vii) Ventless Electric, Combination Washer-Dryer	2.33

II. Introduction

The following section briefly discusses the statutory authority underlying this proposed rule, as well as some of the relevant historical background related to the establishment of standards for consumer clothes dryers.

A. Authority

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include consumer clothes dryers, the subject of this document. (42 U.S.C. 6292(a)(8)) EPCA prescribed energy conservation standards for these products (42 U.S.C. 6295(g)(3)), and directed DOE to conduct future rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(g)(4)) EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions set forth under EPCA. (*See* 42 U.S.C. 6297(d))

Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and 42 U.S.C. 6295(r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding

[3] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0055*.

[4] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0056*.

[5] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0057*.

the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 42 U.S.C. 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for consumer clothes dryers appear at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix D1 and appendix D2 (''appendix D1'' and ''appendix D2,'' respectively).

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including consumer clothes dryers. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary of Energy (''Secretary'') determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

Moreover, DOE may not prescribe a standard if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3) (B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA, as codified, also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. A rule prescribing an energy conservation standard for a type (or class) of product must specify a different standard level for a type or class of product that has the same function or intended use if DOE determines that products within such group: (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE considers such factors as the utility to the consumer of such a feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Additionally, pursuant to the amendments contained in the Energy Independence and Security Act of 2007 (''EISA 2007''), Public Law 110–140, final rules for new or amended energy conservation standards promulgated after July 1, 2010, are required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedures for consumer clothes dryers address standby mode and off mode energy use, as do the standards proposed in this NOPR.

Finally, EISA 2007 amended EPCA, in relevant part, to grant DOE authority to directly issue a final rule (*i.e.,* a ''direct final rule'') establishing an energy or water conservation standard upon receipt of a statement submitted jointly by interested persons that are fairly representative of relevant points of view (including representatives of manufacturers of covered products, States, and efficiency advocates), as determined by the Secretary, that contains recommendations with respect to an energy or water conservation standard. (42 U.S.C. 6295(p)(4)) Pursuant to 42 U.S.C. 6295(p)(4), the Secretary must also determine whether a jointly-submitted recommendation for an energy or water conservation standard satisfies 42 U.S.C. 6295(o) or 42 U.S.C. 6313(a)(6)(B), as applicable.

A NOPR that proposes an identical energy efficiency standard must be published simultaneously with the direct final rule, and DOE must provide a public comment period of at least 110 days on this proposal. (42 U.S.C. 6295(p)(4)(A)–(B)) Based on the comments received during this period, the direct final rule will either become effective, or DOE will withdraw it not later than 120 days after its issuance if (1) one or more adverse comments is received, and (2) DOE determines that those comments, when viewed in light of the rulemaking record related to the direct final rule, may provide a reasonable basis for withdrawal of the direct final rule under 42 U.S.C. 6295(o). (42 U.S.C. 6295(p)(4)(C)) Receipt of an alternative joint recommendation may also trigger a DOE withdrawal of the direct final rule in the same manner. (*Id.*) After withdrawing a direct final rule, DOE must proceed with the NOPR published simultaneously with the direct final rule and publish in the **Federal Register** the reasons why the direct final rule was withdrawn. (*Id.*)

DOE has previously explained its interpretation of its direct final rule authority. In a final rule amending the Department's ''Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products'' at 10 CFR part 430, subpart C, appendix A, DOE noted that it may issue standards recommended by interested persons that are fairly representative of relative points of view as a direct final rule when the recommended standards are in accordance with 42 U.S.C. 6295(o) or 42 U.S.C. 6313(a)(6)(B), as applicable. 86 FR 70892, 70912 (Dec. 13, 2021). But the direct final rule provision in EPCA, under which this proposed rule is issued, does not impose additional requirements applicable to other standards rulemakings, which is consistent with the unique circumstances of rules issued through consensus agreements under DOE's direct final rule authority. *Id.* DOE's discretion remains bounded by its statutory mandate to adopt a standard that results in the maximum improvement in energy efficiency that is technologically feasible and economically justified—a requirement found in 42 U.S.C. 6295(o). *Id. As such, DOE's review and analysis of the Joint Agreement is limited to whether the recommended standards satisfy the criteria in 42 U.S.C. 6295(o).*

B. Background

1. Current Standards

In a direct final rule published on April 21, 2011, (''April 2011 Direct Final Rule'') DOE prescribed the current energy conservation standards for consumer clothes dryers manufactured on and after January 1, 2015. 76 FR 22454.[6] The current energy conservation standards, as amended in the 2011 Direct Final Rule, are in accordance with the appendix D1 test procedure as discussed in section II.B.2 of this document. They are based on combined energy factor (''CEF'')—a metric that incorporates energy use in active mode, standby mode, and off mode.

The current standards are defined in terms of a minimum allowable CEF, as measured according to appendix D1. Even though DOE maintained the same energy efficiency descriptor for both appendix D1 and appendix D2, DOE notes that the CEF values are not equivalent because of the extensive differences in test methods.[7] To avoid potential confusion that would result from using the same efficiency descriptor for both test procedures as it relates to the standards discussed in this document, DOE is including a ''D1'' or ''D2'' subscript when referring to the appendix D1 CEF and appendix D2 CEF, respectively (''CEF_{D1}'' and ''CEF_{D2}'').

TABLE II.1 FEDERAL ENERGY EFFICIENCY STANDARDS FOR CONSUMER CLOTHES DRYERS AS MEASURED UNDER APPENDIX D1

Product class	CEF_{D1} lb/kWh)
(i) Vented Electric, Standard (4.4 ft³ or greater capacity)	3.73
(ii) Vented Electric, Compact (120V) (less than 4.4 ft³ capacity)	3.61
(iii) Vented Electric, Compact (240V) (less than 4.4 ft³ capacity)	3.27
(iv) Vented Gas	3.30
(v) Ventless Electric, Compact (240V) (less than 4.4 ft³ capacity)	2.55
(vi) Ventless Electric, Combination Washer-Dryer	2.08

2. Current Test Procedure

On October 8, 2021, DOE published a final rule for the test procedure rulemaking (86 FR 56608) (the ''October 2021 TP Final Rule''), in which it amended appendix D1 and appendix D2, both entitled ''Uniform Test Method for Measuring the Energy Consumption of Clothes Dryers,'' to provide additional detail in response to questions from manufacturers and test laboratories, including additional detail regarding the testing of ''connected'' models, dryness level selection, and the procedures for maintaining the required heat input rate for gas consumer clothes dryers; additional detail for the test procedures for performing inactive and off mode power measurements; specifications for the final moisture content (''FMC'') required for testing automatic termination control dryers; specification of a narrower scale resolution for the weighing scale used to determine moisture content of test loads; and specification that the test load must be weighed within 5 minutes after a test cycle has terminated. In addition, as part of the October 2021 TP Final Rule, DOE amended the test procedures to update the estimated number of annual use cycles for consumer clothes dryers; provide further direction for additional provisions within the test procedures; specify rounding requirements for all reported values; apply consistent use of nomenclature and correct typographical errors; remove obsolete sections of the test procedures, including appendix D; and update the reference to the applicable industry test procedure to the version certified by the American National Standards Institute (''ANSI''). 86 FR 56608, 56610.

DOE's current energy conservation standards for consumer clothes dryers are expressed in terms of CEF_{D1}. (*See* 10 CFR 430.32(h)(3).) Appendix D1 tests timed drying cycles, and accounts for clothes dryers with automatic termination controls by applying a higher field use factor to units that have this feature. Appendix D2 tests ''normal'' automatic termination cycles and more accurately measure the effects of automatic cycle termination.

EPCA authorizes DOE to design test procedures that measure energy efficiency, energy use, water use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(3)) The appendix D2 test procedure, which is required for use to demonstrate compliance with the amended energy conservation standards established in this direct final rule, measures the energy consumption of a representative use cycle that dries a load of laundry from an initial moisture content of 57.5 percent to an FMC of less than 2 percent. 86 FR 56624–56625. For timer clothes dryers, the test load is

[6] DOE published a confirmation of effective date and compliance date for the direct final rule on August 24, 2011. 76 FR 52854.

[7] While the current standards are based on CEF as determined in accordance with appendix D1, manufacturers are permitted to use the appendix D2 test procedure to comply with the current standards, as long as they use a single appendix for all representations. Beginning on the compliance date of the amended standards established by this final rule, manufacturers will be required to use appendix D2 to comply with the amended standards.

dried until the FMC is between 1 and 2.5 percent of the bone-dry weight of the test load. The measured energy consumption is then normalized to determine the energy consumption required to dry the test load to 2-percent FMC, with a field use factor applied to account for the over-drying energy consumption. For automatic termination control clothes dryers, appendix D2 specifies that a ''normal'' program be selected for the test cycle, and for clothes dryers that do not have a ''normal'' program, the cycle recommended by the manufacturer for drying cotton or linen shall be selected. If the drying temperature and drying level settings can be chosen independently of the program, they shall be set at the maximum drying temperature setting, and at a ''normal'' or ''medium'' dryness level setting. The test is considered valid if the FMC of the test load is 2 percent or less after the completion of the test cycle. If the FMC is greater than 2 percent, the test is considered invalid and a new run shall be conducted using the highest dryness level setting.

The current 2-percent FMC requirement using the DOE test cloth was adopted as representative of approximately 5-percent FMC for ''real-world'' clothing, based on data submitted in a joint petition for rulemaking.[8] DOE determined in the final rule published on August 14, 2013, that established the appendix D2 test procedure that the specified 2-percent FMC using the DOE test load was representative of consumer expectations for dryness of clothing in field use. 78 FR 49608, 49620–49622, 49610–49611. DOE did not amend the FMC requirements in the October 2021 TP Final Rule. 86 FR 56626.

DOE has conducted the rulemaking analysis for this proposed rule based on CEF_{D2} because compliance with the amended energy conservation standards established in the direct final rule published elsewhere in this issue of the **Federal Register** must be determined based on the use of appendix D2. DOE discusses additional details in section IV.C.1 of the accompanying direct final rule about how it developed the engineering baseline, in terms of $CEF_{D2,}$ from the current consumer clothes dryer standards that are in terms of CEF_{D1}.

3. The Joint Agreement

On September 25, 2023, DOE received a joint statement (*i.e.,* the Joint Agreement) recommending standards for consumer clothes dryers, that was submitted by groups representing manufacturers, energy and environmental advocates, consumer groups, and a utility.[9] In addition to the recommended standards for consumer clothes dryers, the Joint Agreement also included separate recommendations for several other covered products.[10] And, while acknowledging that DOE may implement these recommendations in separate rulemakings, the Joint Agreement also stated that the recommendations were recommended as a complete package and each recommendation is contingent upon the other parts being implemented. DOE understands this to mean that the Joint Agreement is contingent upon DOE initiating rulemaking processes to adopt all of the recommended standards in the agreement. That is distinguished from an agreement where issuance of an amended energy conservation standard for a covered product is contingent on issuance of amended energy conservation standards for the other covered products. If the Joint Agreement were so construed, it would conflict with the anti-backsliding provision in 42 U.S.C. 6295(o)(1), because it would imply the possibility that, if DOE were unable to issue an amended standard for a certain product, it would have to withdraw a previously issued standard for one of the other products. The anti-backsliding provision, however, prevents DOE from withdrawing or amending an energy conservation standard to be less stringent. As a result, DOE will be proceeding with individual rulemakings that will evaluate each of the recommended standards separately under the applicable statutory criteria.

A court decision issued after DOE received the Joint Agreement is also relevant to today's rule. On March 17, 2022, various States filed a petition seeking review of a final rule revoking two final rules that established product classes for residential dishwashers with a cycle time for the normal cycle of 60 minutes or less, top-loading residential clothes washers (''RCWs'') and certain classes of consumer clothes dryers with a cycle time of less than 30 minutes, and front-loading RCWs with a cycle time of less than 45 minutes (collectively, ''short cycle product classes''). The petitioners argued that the final rule revoking the short cycle product classes violated EPCA and was arbitrary and capricious. On January 8, 2024, the United States Court of Appeals for the Fifth Circuit granted the petition for review and remanded the matter to DOE for further proceedings consistent with the Fifth Circuit's opinion. *See Louisiana* v. *United States Department of Energy,* 90 F.4th 461 (5th Cir. 2024).

On February 14, 2024, following the Fifth Circuit's decision in *Louisiana* v. *United States Department of Energy,* DOE received a second joint statement from this same group of stakeholders in which the signatories reaffirmed the Joint Agreement, stating that the recommended standards represent the maximum levels of efficiency that are technologically feasible and economically justified.[11] In the letter, the signatories clarified that ''short-cycle'' product classes for RCWs, consumer clothes dryers, and dishwashers did not exist at the time that the signatories submitted their recommendations and it is their understanding that these classes also do not exist at the current time. Accordingly, the parties clarified that the Joint Agreement did not address short-cycle product classes. The signatories also stated that they did not anticipate that the recommended energy conservation standards in the Joint Agreement will negatively affect

[8] The petition was submitted by AHAM, Whirlpool Corporation, General Electric Company, Electrolux, LG Electronics, Inc., BSH, Alliance Laundry Systems, Viking Range, Sub-Zero Wolf, Friedrich A/C, U-Line, Samsung, Sharp Electronics, Miele, Heat Controller, AGA Marvel, Brown Stove, Haier, Fagor America, Airwell Group, Arcelik, Fisher & Paykel, Scotsman Ice, Indesit, Kuppersbusch, Kelon, and DeLonghi, American Council for an Energy Efficient Economy, Appliance Standards Awareness Project, Natural Resources Defense Council, Alliance to Save Energy, Alliance for Water Efficiency, Northwest Power and Conservation Council, and Northeast Energy Efficiency Partnerships, Consumer Federation of America and the National Consumer Law Center. See Docket No. EERE–2011–BT–TP–0054, No. 3.

[9] The signatories to the Joint Agreement include AHAM, American Council for an Energy-Efficient Economy, Alliance for Water Efficiency, Appliance Standards Awareness Project, Consumer Federation of America, Consumer Reports, Earthjustice, National Consumer Law Center, Natural Resources Defense Council, Northwest Energy Efficiency Alliance, and Pacific Gas and Electric Company. Members of AHAM's Major Appliance Division that make the affected products include: Alliance Laundry Systems, LLC; Asko Appliances AB; Beko US Inc.; Brown Stove Works, Inc.; BSH Home Appliances Corporation; Danby Products, Ltd.; Electrolux Home Products, Inc.; Elicamex S.A. de C.V.; Faber; Fotile America; GE Appliances; L'Atelier Paris Haute Design LLG; LG Electronics; Liebherr USA, Co.; Midea America Corp.; Miele, Inc.; Panasonic Appliances Refrigeration Systems (PAPRSA) Corporation of America; Perlick Corporation; Samsung Electronics America Inc.; Sharp Electronics Corporation; Smeg S.p.A; Sub-Zero Group, Inc.; The Middleby Corporation; U-Line Corporation; Viking Range, LLC; and Whirlpool Corporation.

[10] The Joint Agreement contained recommendations for six covered products: refrigerators, refrigerator-freezers, and freezers; residential clothes washers; consumer clothes dryers; dishwashers; consumer conventional cooking products; and miscellaneous refrigeration products.

[11] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058.*

features or performance, including cycle time, for consumer clothes dryers.

In a recently issued request for information (''RFI''),[12] DOE is commencing a rulemaking process on remand from the Fifth Circuit (the ''Remand Proceeding'') by soliciting further information, relevant to the issues identified by the Fifth Circuit, regarding any short cycle product classes. In that Remand Proceeding, DOE will conduct the analysis required by 42 U.S.C. 6295(q)(1)(B) to determine whether any short-cycle products have a ''capacity or other performance-related feature [that] . . . justifies a higher or lower standard from that which applies (or will apply) to other products. . . .''

The Joint Agreement recommends amended standard levels for consumer clothes dryers as presented in Table II.2. (Joint Agreement, No. 55 at p. 9) Details of the Joint Agreement recommendations for other products are provided in the Joint Agreement posted in the docket.[13]

TABLE II.2—RECOMMENDED AMENDED ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

Product class	Minimum energy efficiency ratio (lb/kWh)	Compliance date
Electric, Standard (4.4 cubic feet (''ft^3'') or greater capacity)	3.93	March 1, 2028.
Electric, Compact (120 volts (''V'')) (less than 4.4 ft^3 capacity)	4.33	
Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	3.57	
Vented Gas, Standard (4.4 ft^3 or greater capacity)	3.48	
Vented Gas, Compact (less than 4.4 ft^3 capacity)	2.02	
Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	2.68	
Ventless Electric, Combination Washer-Dryer	2.33	

DOE has evaluated the Joint Agreement and believes that it meets the EPCA requirements for issuance of a direct final rule. As a result, DOE published a direct final rule establishing energy conservation standards for consumer clothes dryers elsewhere in this issue of the **Federal Register**. If DOE receives adverse comments that may provide a reasonable basis for withdrawal and withdraws the direct final rule, DOE will consider those comments and any other comments received in determining how to proceed with this proposed rule. For further background information on these proposed standards and the supporting analyses, please see the direct final rule published elsewhere in this issue of the **Federal Register**. That document and the accompanying technical support document (''TSD'') contain an in-depth discussion of the analyses conducted in evaluating the Joint Agreement, the methodologies DOE used in conducting those analyses, and the analytical results.

When the Joint Agreement was submitted, DOE was conducting a rulemaking to consider amending the standards for consumer clothes dryers. As part of that process, DOE published a NOPR and announced a public webinar to respond to initial comments on August 23, 2022 (''August 2022 NOPR'') seeking comment on its proposed amended standards to inform its decision consistent with its obligations under EPCA and the Administrative Procedures Act (''APA''). 87 FR 51734. DOE subsequently held a public webinar on September 13, 2022, to discuss and receive comments on the August 2022 NOPR TSD. The August 2022 NOPR TSD is available at: *www.regulations.gov/document/EERE-2014-BT-STD-0058-0034.*

III. Proposed Standards

When considering new or amended energy conservation standards, the standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

DOE considered the impacts of amended standards for consumer clothes dryers at each trial standard level (''TSL''), beginning with the maximum technologically feasible (''max-tech'') level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy. DOE refers to this process as the ''walk-down'' analysis.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off upfront costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings as a result of (1) a lack of information; (2) a lack of sufficient salience of the long-term or aggregate benefits; (3) a lack of sufficient savings to warrant delaying or altering purchases; (4) excessive focus on the short term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments; (5) computational or other difficulties associated with the evaluation of relevant tradeoffs; and (6) a divergence in incentives (for example,

[12] See *Appliance Standards Rulemakings and Notices (energy.gov).*

[13] The Joint Agreement available in the docket at *www.regulations.gov/document?D=EERE-2014--BT-STD-0058-0055.*

between renters and owners, or builders and purchasers). Having less than perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher than expected rate between current consumption and uncertain future energy cost savings.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forego the purchase of a product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the manufacturer impact analysis (''MIA''). Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a standard decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the direct final rule TSD [14] available in the docket for this rulemaking. However, DOE's current analysis does not explicitly control for heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or consumer price sensitivity variation according to household income.[15]

A. Benefits and Burdens of TSLs Considered for Consumer Clothes Dryers Standards

Table III.1 and Table III.2 summarize the quantitative impacts estimated for each TSL for consumer clothes dryers. The national impacts are measured over the lifetime of consumer clothes dryers purchased in the 30-year period that begins in the anticipated year of compliance with amended standards (2027–2056).[16] The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle (''FFC'') results. The efficiency levels contained in each TSL are described in section V.A of the direct final rule published elsewhere in this issue of the **Federal Register**. DOE is presenting monetized benefits of greenhouse gas (''GHG'') emissions reductions in accordance with the applicable Executive Orders and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the Interim Estimates presented by the Interagency Working Group. The efficiency levels contained in each TSL are described in section V.A of the direct final rule published elsewhere in this issue of the **Federal Register**.

TABLE III.1—SUMMARY OF ANALYTICAL RESULTS FOR CONSUMER CLOTHES DRYER TSLS: NATIONAL IMPACTS

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Cumulative FFC National Energy Savings						
Quads	0.57	1.58	2.66	3.52	9.70	9.76
Cumulative FFC Emissions Reduction						
CO_2 (million metric tons)	12.4	34.1	57.1	73.5	188.6	189.6
CH_4 (thousand tons)	114.8	311.4	527.6	661.6	1,646	1,654
N_2O (thousand tons)	0.1	0.3	0.5	0.6	1.7	1.7
NO_X (thousand tons)	25.4	69.0	116.5	146.7	364.1	366.0
SO_2 (thousand tons)	3.0	8.4	13.9	19.0	53.3	53.6
Hg (tons)	0.02	0.1	0.1	0.1	0.4	0.4
Present Value of Benefits and Costs (3% discount rate, billion 2022$)						
Consumer Operating Cost Savings	4.3	12.7	21.1	28.8	77.4	77.8
Climate Benefits*	0.7	2.0	3.3	4.3	10.8	10.9
Health Benefits**	1.4	3.8	6.3	8.2	20.8	20.9
Total Benefits†	6.4	18.5	30.7	41.3	108.9	109.5
Consumer Incremental Product Costs‡	0.2	0.4	1.0	8.9	46.2	47.3
Consumer Net Benefits	4.1	12.3	20.1	19.9	31.2	30.5
Total Net Benefits	6.2	18.2	29.7	32.4	62.8	62.2
Present Value of Benefits and Costs (7% discount rate, billion 2022$)						
Consumer Operating Cost Savings	2.0	6.1	9.8	13.7	35.2	35.4
Climate Benefits*	0.7	2.0	3.3	4.3	10.8	10.9
Health Benefits**	0.6	1.7	2.6	3.6	8.7	8.7
Total Benefits†	3.4	9.8	15.8	21.6	54.7	55.0
Consumer Incremental Product Costs‡	0.1	0.2	0.6	5.3	26.2	26.8
Consumer Net Benefits	1.9	5.9	9.2	8.4	9.0	8.6

[14] The TSD is available in the docket for this rulemaking at *www.regulations.gov/docket/EERE-2014-BT-STD-0058/document.*

[15] P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies.* 2005. 72(3): pp. 853–883. doi: *10.1111/0034–6527.00354.*

[16] The analysis period for TSL 3 (the Recommended TSL) is 2028–2057.

TABLE III.1—SUMMARY OF ANALYTICAL RESULTS FOR CONSUMER CLOTHES DRYER TSLS: NATIONAL IMPACTS—Continued

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Total Net Benefits	3.3	9.6	15.2	16.3	28.5	28.2

Note: This table presents the costs and benefits associated with consumer clothes dryers shipped during the period 2027–2056 for all TSLs except TSL 3 (the Recommended TSL) and 2028–2057 for TSL 3. These results include consumer, climate, and health benefits that accrue after 2056 from the products shipped during the period 2027–2056 for all TSLs except TSL 3 and 2057 from the products shipped during the period 2028–2057 for TSL 3.

* Climate benefits are calculated using four different estimates of the four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5-percent, 3-percent, and 5-percent discount rates; 95th percentile at 3-percent discount rate). Together, these represent the global SC–GHG. For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown; however, DOE emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the Interagency Working Group (''IWG'') on the Social Cost of Greenhouse Gases. *See www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocumentSocialCostofCarbonMethaneNitrousOxide.pdf.*

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for NO_X and SO_2) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. For more details, see section IV.L of the direct final rule published elsewhere in this issue of the FEDERAL REGISTER.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate.

‡ Costs include incremental equipment costs as well as installation costs.

TABLE III.2—SUMMARY OF ANALYTICAL RESULTS FOR CONSUMER CLOTHES DRYER TSLS: MANUFACTURER AND CONSUMER IMPACTS

Category	TSL 1 *	TSL 2 *	TSL 3 *	TSL 4 *	TSL 5 *	TSL 6 *
Manufacturer Impacts						
Industry NPV (million 2022$) (No-new-standards case INPV = 2,115.4).	2,080.3 to 2,084.3	2,061.1 to 2,069.5	1,971.2 to 1,995.8	1,501.9 to 1,724.8	679.9 to 1,800.8	604.3 to 1,753.5.
Industry NPV (% change)	(1.7) to (1.5)	(2.6) to (2.2)	(6.8) to (5.7)	(29.0) to (18.5)	(67.9) to (14.9)	(71.4) to (17.1).
Consumer Average LCC Savings (2022$)						
Electric, Standard	$150	$170	$252	$101	$41	$41
Electric, Compact (120 V)	$53	$83	$66	$66	$66	($209)
Vented Electric, Compact (240 V)	$38	$89	$90	$90	$22	($230)
Vented Gas, Standard	$48	$112	$102	$102	$13	$13
Ventless Electric, Compact (240 V)	$0	$99	$99	$99	$99	($102)
Ventless Electric, Combination Washer-Dryer.	$0	$10	$11	$10	$10	($531)
Shipment-Weighted Average *	$131	$159	$224	$100	$36	$29
Consumer Simple PBP (years)						
Electric, Standard	0.5	0.5	0.6	2.1	5.8	5.8
Electric, Compact (120 V)	1.5	1.5	2.2	2.2	2.2	18.1
Vented Electric, Compact (240 V)	2.1	1.5	2.0	2.0	6.6	20.4
Vented Gas, Standard	2.5	1.3	1.9	1.9	5.0	5.0
Ventless Electric, Compact (240 V)	0.0	0.4	0.4	0.4	0.4	11.4
Ventless Electric, Combination Washer-Dryer.	0.0	0.0	0.0	0.0	0.0	46.3
Shipment-Weighted Average *	0.9	0.6	0.8	2.1	5.6	6.1
Percent of Consumers that Experience a Net Cost						
Electric, Standard	1.2%	0.9%	0.9%	48.0%	63.1%	63.1%
Electric, Compact (120 V)	4.8%	5.1%	21.4%	21.7%	21.7%	90.9%
Vented Electric, Compact (240 V)	5.7%	4.6%	12.4%	12.6%	60.7%	92.8%
Vented Gas, Standard	2.7%	1.7%	7.1%	7.0%	68.7%	68.7%
Ventless Electric, Compact (240 V)	0.0%	0.0%	0.0%	0.0%	0.0%	58.6%
Ventless Electric, Combination Washer-Dryer.	0.0%	0.0%	0.0%	0.0%	0.0%	95.0%
Shipment-Weighted Average *	1.5%	1.0%	2.0%	40.4%	63.3%	64.5%

Parentheses indicate negative (-) values.

* Weighted by shares of each product class in total projected shipments in 2027 for all TSLs except TSL 3 and in 2028 for TSL 3.

DOE first considered TSL 6, which represents the max-tech efficiency level and includes the design parameters of the most efficient products available on the market or in working prototypes for all product classes. The max-tech design options include heat pump technology for electric consumer clothes dryers and inlet air preheat technology for gas consumer clothes dryers. DOE's shipments analysis estimates approximately 1 percent of annual consumer clothes dryer shipments currently meet this level. TSL 6 would save an estimated 9.76 quadrillion British thermal units (''quads'') of energy, an amount DOE considers significant. Under TSL 6, the net present value (''NPV'') of consumer benefit would be $8.6 billion using a discount

rate of 7 percent, and $30.5 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 6 would be 189.6 million tons (''Mt'') of CO_2, 53.6 thousand tons of SO_2, 366.0 thousand tons of NO_X, 0.4 ton of Hg, 1,654 thousand tons of CH_4, and 1.7 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 6 would be $10.9 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 6 would be $8.7 billion using a 7-percent discount rate and $20.9 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 6 would be $28.2 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 6 would be $62.2 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At TSL 6, the average life-cycle cost (''LCC'') impact on affected consumers would be a savings of $41 for electric standard, −$209 for electric compact (120V), −$230 for vented electric compact (240V), $13 for vented gas standard, −$102 for ventless electric compact (240V), and −$531 for ventless electric combination washer-dryer. The simple payback period (''PBP'') would be 6 years for electric standard, 18 years for electric compact (120V), 20 years for vented electric compact (240V), 5 years for vented gas standard, 11 years for ventless electric compact (240V), and 46 years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost would be 63 percent for electric standard, 91 percent for electric compact (120V), 93 percent for vented electric compact (240V), 69 percent for vented gas standard, 59 percent for ventless electric compact (240V), and 95 percent for ventless electric combination washer-dryer. Overall, across the product classes, the majority of consumers would experience a net LCC cost, especially for senior households. DOE estimated that more 72 percent of senior-only households would experience a net LCC cost at TSL 6.

At TSL 6, the projected change in industry net present value (''INPV'') ranges from a decrease of $1,511.1 million to a decrease of $361.9 million, corresponding to decreases of 71.4 percent and 17.1 percent, respectively. The loss in INPV is largely driven by industry conversion costs as manufacturers work to redesign their portfolios of model offerings and retool entire factories to comply with amended standards at this level. Industry conversion costs could reach $1,516.9 million at this TSL.

Conversion costs at TSL 6 are significant as nearly all existing consumer clothes dryer models would need to be redesigned to meet the max-tech efficiencies. Approximately 1 percent of industry shipments currently meet TSL 6. For the electric clothes dryer product classes, manufacturers would need to implement heat pump technology to meet max-tech levels. Out of the 19 original equipment manufacturers (''OEMs'') that manufacture electric consumer clothes dryers, nine OEMs offer heat pump models for the U.S. market. The remaining 10 OEMs do not offer any models for the domestic market that utilize heat pump technology. A standard that could only be met using heat pump technology would require a total renovation of existing production facilities and would require most manufacturers to design completely new clothes dryer platforms, as they would not be able to maintain the resistive heating designs that currently dominate the U.S. electric clothes dryer market. In interviews, several manufacturers expressed concern about a potential shortage of products given the required scale of investment, redesign efforts, and 3-year compliance timeline.

For gas consumer clothes dryers, manufacturers would need to implement inlet air preheat technology along with other design options to meet the efficiency levels required by TSL 6. Thus far, consumer clothes dryers with this technology and performance have not been observed in consumer clothes dryers available on the consumer market. Consumer clothes dryers with inlet air preheat designs have been observed only in laboratory settings. In interviews, some manufacturers raised concerns about implementing a relatively untested technology for the consumer market. There is very little industry experience with inlet air preheat designs. Several manufacturers speculated that implementing inlet air preheat technology would require a major overhaul of existing production facilities and a significant amount of engineering time.

At this level, DOE estimates an 11-percent drop in shipments in the year the standard would take effect compared to the no-new-standards case, as price-sensitive consumers may forgo purchasing a new clothes dryer or rely on alternatives such as repair or purchasing a used dryer due to the increased upfront cost of baseline models.

The Secretary tentatively concludes that at TSL 6 for consumer clothes dryers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on many consumers, especially senior-only households, as well as the impacts on manufacturers, including the potential for large conversion costs and reduction in INPV.

TSL 6, representing the most efficient heat pump technology on the market, would provide significant energy savings potential, as discussed. Despite the current and potential future benefits of heat pump technology, the analysis at TSL 6 indicates that a significant fraction of consumers of electric and vented gas standard clothes dryers, including low-income and senior-only households, would experience a net cost given the current relatively high incremental cost of electric and vented gas standard clothes dryers at the max-tech efficiency level. This is particularly pronounced for electric standard clothes dryers, where the incremental production cost at the max-tech efficiency level is comparable to the manufacturer production cost for the baseline efficiency level. Consumers with existing electric standard clothes dryers below EL 4 (about 55 percent) and consumers with existing vented gas standard clothes dryers below EL 3 (about 50 percent) would be more likely to experience a net cost at TSL 6, given the relatively modest decrease in operating costs compared to the high incremental installed costs. Few products currently meet the efficiency levels required by TSL 6. DOE estimates that approximately 1 percent of current shipments meet the max-tech efficiencies. At max-tech, limited industry experience by certain manufacturers with the high-efficiency design options, the large conversion costs to update facilities and product designs, and expected drop in industry shipments would result in a reduction of INPV and a potential shortage of products given the required scale of investment, redesign efforts, and time constraints. Consequently, the Secretary has tentatively concluded that TSL 6 is not economically justified.

DOE then considered TSL 5, which represents the maximum energy savings with positive NPV. TSL 5 corresponds

to the max-tech level (EL 7), which represents heat pump technology, for the electric standard product class, and the efficiency levels corresponding to modulating (2-stage) heating technology in the electric compact (120V) and inlet air preheat technology in the vented electric compact (240V) product classes considered in this analysis. For the vented gas standard product class, TSL 5 corresponds to the max-tech level (EL 4), which represents inlet air preheat technology. TSL 5 would save an estimated 9.70 quads of energy, an amount DOE considers significant. Under TSL 5, the NPV of consumer benefit would be $9.0 billion using a discount rate of 7 percent, and $31.2 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 5 would be 188.6 Mt of CO_2, 53.3 thousand tons of SO_2, 364.1 thousand tons of NO_X, 0.4 ton of Hg, 1,646 thousand tons of CH_4, and 1.7 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 5 would be $10.8 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 5 would be $ 8.7 billion using a 7-percent discount rate and $20.8 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 5 would be $28.5 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 5 would be $62.8 billion. The estimated total NPV is provided for additional information, however DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At TSL 5, the average LCC impact on affected consumers would be a savings of $41 for electric standard, $66 for electric compact (120V), $22 for vented electric compact (240V), $13 for vented gas standard, $99 for ventless electric compact (240V), and $10 for ventless electric combination washer-dryer. The simple PBP would be 6 years for electric standard, 2 years for electric compact (120V), 7 years for vented electric compact (240V), 5 years for vented gas standard, 0.4 years for ventless electric compact (240V), and zero years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost would be 63 percent for electric standard, 22 percent for electric compact (120V), 61 percent for vented electric compact (240V), 69 percent for vented gas standard, and zero percent for ventless electric compact (240V) and ventless electric combination washer-dryer. Overall, across the product classes, approximately 63 percent of consumers would experience a net LCC cost, especially for senior-only households. DOE estimated that more than 71 percent of senior-only households would experience a net LCC cost at TSL 5.

At TSL 5, the projected change in INPV ranges from a decrease of $1,435.5 million to a decrease of $314.6 million, corresponding to decreases of 67.9 percent and 14.9 percent, respectively. Industry conversion costs could reach $1,436.9 million at this TSL.

DOE's shipments analysis estimates approximately 2 percent of annual shipments currently meet this level. At TSL 5, the efficiency levels and analyzed design options for electric standard and vented gas standard dryers (which together account for approximately 98 percent of industry shipments) are the same as at max-tech. Thus, requiring heat pump technology for electric standard dryers and inlet air preheat for vented gas standard dryers would result in similar conversion costs, reduction in INPV, and drop in shipments as TSL 6.

At this level, DOE estimates an 11-percent drop in shipments in the year the standard would take effect compared to the no-new-standards case, as price-sensitive consumers may forgo purchasing a new clothes dryer or rely on alternatives such as repair or purchasing a used dryer due to the increased upfront cost of baseline models.

The Secretary tentatively concludes that at TSL 5 for consumer clothes dryers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on many consumers, especially senior-only households, as well as the impacts on manufacturers, including the significant conversion costs and large potential reduction in INPV. A significant fraction of electric standard clothes dryer consumers, including low-income and senior-only households, would experience a net cost. This is due to the high incremental cost of electric standard clothes dryers at the max-tech efficiency level. Consumers with existing electric standard clothes dryers below EL 4 would be more likely to experience a net cost at TSL 5, given the relatively modest decrease in operating costs compared to the high incremental installed costs. DOE estimates that approximately 2 percent of shipments currently meet the efficiencies required by this TSL. At TSL 5, the limited industry experience by certain manufacturers with the high-efficiency design options, the large conversion costs to update facilities and product designs, and expected drop in industry shipments would result in a reduction of INPV and a potential shortage of products given the required scale of investment, redesign efforts, and time constraints. Consequently, the Secretary has tentatively concluded that TSL 5 is not economically justified.

DOE then considered TSL 4, which represents the maximum national energy savings with simple PBP less than 4 years for each product class. TSL 4 corresponds to the EL that represents inlet air preheat technology for the electric standard product class considered in this analysis. For the electric compact (120V) and vented electric compact (240V) product classes, TSL 4 corresponds to EL 4, which represents modulating (2-stage) heating technology. For the vented gas standard product class, TSL 4 corresponds to EL 3, which also represents modulating (2-stage) heating technology. TSL 4 would save an estimated 3.52 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be $8.4 billion using a discount rate of 7 percent, and $19.9 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 would be 73.5 Mt of CO_2, 19.0 thousand tons of SO_2, 146.7 thousand tons of NO_X, 0.1 ton of Hg, 661.6 thousand tons of CH_4, and 0.6 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 4 would be $4.3 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 4 would be $3.6 billion using a 7-percent discount rate and $8.2 million using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 4 would be $16.3 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 4 would be $32.4 billion. The estimated total NPV is

provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At TSL 4, the average LCC impact on affected consumers would be a savings of $101 for electric standard, $66 for electric compact (120V), $90 for vented electric compact (240V), $102 for vented gas standard, $99 for ventless electric compact, and $10 for ventless electric combination washer-dryer. The simple PBP would be 2 years for electric standard, 2 years for electric compact (120V), 2 years for vented electric compact (240V), 2 years for vented gas standard, 0.4 years for ventless electric compact (240V), and zero years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost would be 48 percent for electric standard, 22 percent for electric compact (120V), 13 percent for vented electric compact (240V), 7 percent for vented gas standard, and zero percent for ventless electric compact (240V) and ventless electric combination washer-dryer. Overall, across the product classes, approximately 40 percent of consumers would experience a net LCC cost, especially for senior households. DOE estimated that about 45 percent of senior-only households would experience a net LCC cost at TSL 4.

At TSL 4, the projected change in INPV ranges from a decrease of $613.5 million to a decrease of $390.6 million, corresponding to decreases of 29.0 percent and 18.5 percent, respectively. Industry conversion costs could reach $667.5 million at this TSL.

At TSL 4, the majority of consumer clothes dryer models would need to be redesigned to meet the efficiency levels required. DOE's shipments analysis estimates approximately 15 percent of current shipments meet this level. For electric standard dryers, the design options include implementing inlet air preheat and other features. As previously noted, electric standard dryers account for approximately 81 percent of total shipments. At the current time, there is very little industry experience with inlet air preheat designs. Currently, DOE is not aware of any consumer clothes dryers on the market utilizing this design option. DOE's shipments analysis estimates that approximately 7 percent of electric standard shipments currently meet the efficiency required by TSL 4. Implementing inlet air preheat for electric standard dryers would represent a major overhaul of existing product lines and manufacturing facilities. This change would necessitate significant investments in new equipment and tooling. Product conversion costs would be necessary for designing, prototyping, and testing new or updated platforms.

For vented gas standard clothes dryers, the analyzed design option at TSL 4 includes modulating (2-stage) heat technology, among other design options. Out of the nine OEMs that manufacture vented gas standard clothes dryers, eight offer products that meet the efficiencies required at TSL 4. DOE does not believe that there are any substantive barriers to modulating (2-stage) heating technology. Capital conversion costs would be necessary as manufacturers increase tooling for 2-stage heating systems. Product conversion costs would be necessary for cost-optimizing and testing new designs for a market with potential amended standards.

At this level, DOE does not expect a notable drop in shipments in the year the standard takes effect.

The Secretary tentatively concludes that at TSL 4 for consumer clothes dryers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on many consumers, especially senior-only households, as well as the impacts on manufacturers, including the conversion costs and profit margin impacts that could result in a large reduction in INPV. A significant fraction of electric standard clothes dryer consumers, including senior-only households, would experience a net cost. This is due to the high incremental cost of electric standard clothes dryers at the inlet air preheat technology efficiency level. Consumers with existing electric standard clothes dryers below EL 4 would be more likely to experience a net cost at TSL 4, given the relatively modest decrease in operating costs compared to the high incremental installed costs. For electric standard dryers, DOE estimates that approximately 7 percent of shipments currently meet the efficiency level required by this TSL. At TSL 4, the limited industry experience of electric standard dryer manufacturers with inlet air preheat technology and the large conversion costs to update facilities and product designs, would result in a large reduction of INPV. Consequently, the Secretary has tentatively concluded that TSL 4 is not economically justified.

DOE then considered TSL 3, which corresponds to the TSL recommended in the Joint Agreement (the ''Recommended TSL'') and, which also represents a set of intermediate efficiency levels between those designated in TSL 2 and TSL 4 and corresponds to the current ENERGY STAR efficiency levels for the electric standard and vented gas standard product classes, which represent approximately 98 percent of the market. The Recommended TSL corresponds to the EL that represents modulating (2-stage) heating technology for the electric standard and electric compact (120V) product classes. For the vented gas standard product class, the Recommended TSL corresponds to EL 3, which also represents modulating (2-stage) heating technology. For the vented gas compact product class, the Recommended TSL corresponds to baseline CEF_{D2}. For the electric compact (240V) product classes, the Recommended TSL corresponds to EL 2 for vented consumer clothes dryers, which represents a model with an optimized heating system and EL 1 for ventless consumer clothes dryers, which represents a baseline model with a more advanced automatic termination control system. For the ventless electric combination washer-dryer product class, the Recommended TSL corresponds to EL 1, which represents a baseline model with high-speed spin technology. The Recommended TSL would save an estimated 2.66 quads of energy, an amount DOE considers significant. Under the Recommended TSL, the NPV of consumer benefit would be $9.23 billion using a discount rate of 7 percent, and $20.08 billion using a discount rate of 3 percent.

The cumulative emissions reductions at the Recommended TSL would be 57.1 Mt of CO_2, 13.9 thousand tons of SO_2, 116.5 thousand tons of NO_X, 0.1 ton of Hg, 527.6 thousand tons of CH_4, and 0.5 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 3 would be $3.3 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 3 would be $2.6 billion using a 7-percent discount rate and $6.3 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at the Recommended TSL would be $15.2 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at the Recommended TSL would be $29.7 billion. The estimated total NPV is provided for additional information;

however, DOE primarily relies upon the NPV of consumer benefits when determining whether a standard level is economically justified.

At the Recommended TSL, the average LCC impact on affected consumers would be a savings of $252 for electric standard, $66 for electric compact (120V), $90 for vented electric compact (240V), $102 for vented gas standard, $99 for ventless electric compact, and $11 for ventless electric combination washer-dryer. The simple PBP would be 1 year for the largest product class (electric standard), 2 years for electric compact (120V), 2 years for vented electric compact (240V), 2 years for vented gas standard, 0.4 years for ventless electric compact (240V), and zero years for ventless electric combination washer-dryer. The fraction of consumers experiencing a net LCC cost would be 1 percent for electric standard, 21 percent for electric compact (120V), 12 percent for vented electric compact (240V), 7 percent for vented gas standard, and zero percent for ventless electric compact (240V) and ventless electric combination washer-dryer. Overall, across the product classes, approximately 2 percent of consumers, including low-income and senior-only households, would experience a net LCC cost.

At the Recommended TSL, the projected change in INPV ranges from a decrease of $144.2 million to a decrease of $119.7 million, corresponding to decreases of 6.8 percent and 5.7 percent, respectively. Industry conversion costs could reach $180.7 million at this TSL.

DOE expects that some existing consumer clothes dryer models would need to be redesigned to meet the Recommended TSL efficiencies, but there are a wide range of available models for vented electric standard dryers due to participation in the ENERGY STAR program. DOE's shipments analysis estimates approximately 48 percent of annual shipments currently meet this level. For electric standard, electric compact (120V), vented electric compact (240V), and vented gas standard clothes dryers, which account for approximately 99 percent of total annual shipments, the design options include implementing electronic controls, optimized heating systems, more advanced automatic termination controls, and modulating (2-stage) heat. Of the 19 electric dryer OEMs, 14 offer products at or above the efficiencies required for the electric dryer product classes at the Recommended TSL. Out of the nine OEMs that manufacture vented gas standard clothes dryers, eight offer products that meet the efficiencies required at the Recommended TSL. Capital conversion costs may be necessary as manufacturers increase tooling for 2-stage heating systems. Manufacturers may choose to further cost-optimize and test new designs as a result of the standards, but DOE believes some of this has already occurred in response to ENERGY STAR. DOE does not expect any drop in shipments in the year the standard takes effect.

For all TSLs considered in this NOPR—except for the Recommended TSL—DOE is bound by the 3-year lead time requirements in EPCA when determining compliance dates (*i.e.,* compliance with amended standards required in 2027). For the Recommended TSL, DOE's analysis utilized the March 1, 2028, compliance date specified in the Joint Agreement as it was an integral part of the multi-product joint recommendation. A 2028 compliance year would provide manufacturers additional flexibility to spread capital requirements, engineering resources, and conversion activities over a longer period of time depending on the individual needs of each manufacturer.

At the Recommended TSL, DOE's data demonstrate no negative impact on consumer utility for consumer clothes dryers. In addition, the second joint statement from the same group of stakeholders that submitted the Joint Agreement states that DOE's test data show, and industry experience agrees, that the recommended standard level for consumer clothes dryers will not result in significant differences in cycle time and will adequately dry clothes.[17] Based on the information available, DOE concludes that no lessening of product utility or performance would occur at the Recommended TSL.

After considering the analysis and weighing the benefits and burdens, the Secretary has tentatively concluded that a standard set at the Recommended TSL for consumer clothes dryers would result in the maximum improvement in energy efficiency that is technologically feasible and economically justified and also result in the significant conservation of energy. At this TSL, the average LCC savings for all consumer clothes dryer product classes would be positive. An estimated weighted average of 2 percent of consumer clothes dryer consumers would experience a net cost. The FFC national energy savings would be significant and the NPV of consumer benefits would be positive using both a 3-percent and 7-percent discount rate. Notably, the benefits to consumers would vastly outweigh the cost to manufacturers. At the Recommended TSL, the NPV of consumer benefits, even measured at the more conservative discount rate of 7 percent, would be over 64 times higher than the maximum estimated manufacturers' loss in INPV. The positive LCC savings—a different way of quantifying consumer benefits—reinforces this conclusion. The standard levels at the Recommended TSL are economically justified even without weighing the estimated monetary value of emissions reductions. When those emissions reductions are included—representing $3.3 billion in climate benefits (associated with the average SC–GHG at a 3-percent discount rate), and $6.3 billion (using a 3-percent discount rate) or $2.6 billion (using a 7-percent discount rate) in health benefits—the rationale becomes stronger still.

As stated, DOE conducts the walk-down analysis to determine the TSL that represents the maximum improvement in energy efficiency that is technologically feasible and economically justified as required under EPCA. The walk-down is not a comparative analysis, as a comparative analysis would result in the maximization of net benefits instead of energy savings that are technologically feasible and economically justified, which would be contrary to the statute. 86 FR 70892, 70908. Although DOE has not conducted a comparative analysis to select the proposed amended energy conservation standards, DOE notes that as compared to TSL 6, TSL 5, and TSL 4, the Recommended TSL would have higher average LCC savings, smaller percentages of consumers experiencing a net cost, a lower maximum decrease in INPV, and lower manufacturer conversion costs.

Although DOE considered amended standard levels for consumer clothes dryers by grouping the efficiency levels for each product class into TSLs, DOE evaluates all analyzed efficiency levels in its analysis. Accordingly, the Secretary has tentatively concluded that the Recommended TSL would offer the maximum improvement in efficiency that is technologically feasible and economically justified and would result in the significant conservation of energy. For electric standard and vented gas standard consumer clothes dryers, which account for approximately 98 percent of U.S. shipments, requiring efficiency levels above the levels required by the Recommended TSL would result in a large percentage of consumers experiencing a net LCC cost, in addition to significant manufacturer

[17] This document is available in the docket at: *www.regulations.gov/comment/EERE-2014-BT-STD-0058-0058.*

impacts and reductions in INPV. Additionally, for consumer clothes dryers, most manufacturers offer products that can meet the Recommended TSL across both electric and gas consumer clothes dryers. In addition, the Recommended TSL corresponds to the current ENERGY STAR levels for electric standard and vented gas standard clothes dryers, which have significant market share and manufacturer support due to their promotion over the past couple of years as a voluntary energy efficiency program. The adoption of standards, if finalized, at this TSL may encourage ENERGY STAR to further consider more efficient levels for dryers in the year leadings up to the compliance of date of the standard, which would in turn likely spur additional market introductions of consumer clothes dryers with heat pump technology, foster maturation of the technology and downward price trends, and further support differentiation within the dryer market for energy efficient products. For electric and vented gas standard consumer clothes dryers, the Recommended TSL is comprised of EL 4 and EL 3, respectively, resulting in higher LCC savings, a significant reduction in the number of consumers experiencing a net cost, a lower maximum decrease in INPV, and lower conversion costs to the point where DOE has tentatively concluded they are economically justified, as discussed for the Recommended TSL in the preceding paragraphs.

Therefore, based on the previous considerations, DOE proposes the energy conservation standards for consumer clothes dryers at the Recommended TSL.

While DOE considered each potential TSL under the criteria laid out in 42 U.S.C. 6295(o) as discussed in the preceding paragraphs, the Recommended TSL for consumer clothes dryers proposed in this NOPR is part of a multi-product Joint Agreement covering six rulemakings (residential clothes washers; consumer clothes dryers; consumer conventional cooking products; dishwashers; refrigerators, refrigerator-freezers, and freezers; and miscellaneous refrigeration products). The signatories indicate that the Joint Agreement for the six rulemakings should be considered as a joint statement of recommended standards, to be adopted in its entirety. As discussed in section V.B.2.e of the direct final rule published elsewhere in this issue of the **Federal Register**, many consumer clothes dryer OEMs also manufacture residential clothes washers; consumer conventional cooking products; dishwashers; refrigerators, refrigerator-freezers, and freezers; and miscellaneous refrigeration products. Therefore, there are potential integrated benefits to the Joint Agreement. Rather than requiring compliance with five amended standards in a single year (2027),[18] the negotiated multi-product Joint Agreement staggers the compliance dates for the five amended standards over a 4-year period (2027–2030). DOE understands that the compliance dates recommended in the Joint Agreement would help reduce cumulative regulatory burden by allowing greater flexibility in the allocation of resources to comply with multiple concurrent amended standards and by aligning compliance dates for products that are typically designed or sold as matched pairs (*i.e.,* clothes washers and clothes dryers). The Joint Agreement also provides additional years of regulatory certainty for manufacturers and their suppliers while still achieving the maximum improvement in energy efficiency that is technologically feasible and economically justified.

The proposed amended energy conservation standards for consumer clothes dryers, which are expressed as CEF_{D2}, are shown in Table III.3.

TABLE III.3—PROPOSED AMENDED ENERGY CONSERVATION STANDARDS FOR CONSUMER CLOTHES DRYERS

Product class	CEFD2 (lb/kWh)
(i) Electric, Standard (4.4 ft3 or greater capacity)	3.93
(ii) Electric, Compact (120V) (less than 4.4 ft3 capacity)	4.33
(iii) Vented Electric, Compact (240V) (less than 4.4 ft3 capacity)	3.57
(iv) Vented Gas, Standard (4.4 ft3 or greater capacity)	3.48
(v) Vented Gas, Compact (less than 4.4 ft3 capacity)	2.02
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft3 capacity)	2.68
(vii) Ventless Electric, Combination Washer-Dryer	2.33

B. Annualized Benefits and Costs of the Proposed Standards

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The annualized net benefit is (1) the annualized national economic value (expressed in 2022$) of the benefits from operating products that meet the proposed standards (consisting primarily of operating cost savings from using less energy, minus increases in product purchase costs, and (2) the annualized monetary value of the climate and health benefits from emission reductions.

Table II.4 shows the annualized values for consumer clothes dryers under the Recommended TSL, expressed in 2022$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and NO_X and SO_2 reductions, and the 3-percent discount rate case for GHG social costs, the estimated cost of the proposed standards for consumer clothes dryers would be $60.0 million per year in increased equipment installed costs, while the estimated annual benefits would be $971.4 million from reduced equipment operating costs, $185.5 million in GHG reductions, and $259.9 million from reduced NO_X and SO_2 emissions. In this case, the net benefit would amount to $1,357 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the proposed standards for consumer clothes dryers would be $57.2 million per year in increased equipment costs, while the estimated annual benefits would be $1,177 million in reduced operating costs, $185.5 million from GHG reductions, and $349.4 million from reduced NO_X and SO_2 emissions. In this case, the net benefit would amount to $1,654 million per year.

[18] The analyses for residential clothes washers (88 FR 13520); consumer clothes dryers (87 FR 51734); consumer conventional cooking products (88 FR 6818); dishwashers (88 FR 32514); and refrigerators, refrigerator-freezers, and freezers (88 FR 12452) utilized a 2027 compliance year for analysis at the proposed rule stage. Miscellaneous refrigeration products (88 FR 12452) utilized a 2029 compliance year for the NOPR analysis.

TABLE II.4—ANNUALIZED BENEFITS AND COSTS OF PROPOSED STANDARDS FOR CONSUMER CLOTHES DRYERS

	Million 2022$/year		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	1,177	1,103	1,230
Climate Benefits *	185.5	178.9	187.8
Health Benefits **	349.4	337.2	353.7
Total Benefits †	1,712	1,619	1,771
Consumer Incremental Product Costs ‡	57.2	58.9	54.4
Net Benefits	1,654	1,560	1,717
Change in Producer Cashflow (INPV‡‡)	(12)–(10)	(12)–(10)	(12)–(10)
7% discount rate			
Consumer Operating Cost Savings	971.4	915.5	1,014
Climate Benefits *	185.5	178.9	187.8
Health Benefits **	259.9	251.5	262.8
Total Benefits †	1,417	1,346	1,464
Consumer Incremental Product Costs ‡	60.0	61.2	57.7
Net Benefits	1,357	1,285	1,407
Change in Producer Cashflow (INPV‡‡)	(12)–(10)	(12)–(10)	(12)–(10)

Note: This table presents the costs and benefits associated with consumer clothes dryers shipped during the period 2028–2057. These results include benefits to consumers which accrue after 2057 from the products shipped during the period 2028–2057. The Primary, Low-Net-Benefits, and High-Net-Benefits estimates utilize projections of energy prices from the *AEO2023* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a constant rate in the Low-Net-Benefits Estimate, and a high decline rate in the High-Net-Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.H.3 of the direct final rule published elsewhere in this issue of the **Federal Register**. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC–GHG (see section IV.L of the direct final rule published elsewhere in this issue of the **Federal Register**). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. *See* section IV.L of the direct final rule published elsewhere in this issue of the **Federal Register** for more details.

† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate.

‡ Costs include incremental equipment costs as well as installation costs.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis. *See* sections IV.F and IV.H of the direct final rule published elsewhere in this issue of the **Federal Register**. DOE's NIA includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (the MIA). *See* section IV.J of the direct final rule published elsewhere in this issue of the **Federal Register** and chapter 12 of the direct final rule TSD. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 7.5 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the direct final rule TSD for a complete description of the industry weighted average cost of capital). For consumer clothes dryers, those values are −$12 million to −$10 million. DOE accounts for that range of likely impacts in analyzing whether a TSL is economically justified. *See* section V.C of the direct final rule published elsewhere in this issue of the **Federal Register**. DOE is presenting the range of impacts to the INPV under two manufacturer markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table, and the Preservation of Operating Profit scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in chapter 12 of the direct final rule TSD, to provide additional context for assessing the estimated impacts of this proposed rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this proposed rule, the annualized net benefits would range from $1,642 million to $1,644 million at 3-percent discount rate and would range from $1,345 million to $1,347 million at 7-percent discount rate. Parentheses ( ) indicate negative values.

IV. Public Participation

A. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule until the date provided in the **DATES** section at the beginning of this proposed rule. 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. Comments relating to the direct final rule published elsewhere in this issue of the **Federal Register**, should be submitted as instructed therein.

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 Building Technologies 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 telefacsimiles (''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).

B. Public Meeting

As stated previously, if DOE withdraws the direct final rule published elsewhere in this issue of the **Federal Register** pursuant to 42 U.S.C. 6295(p)(4)(C), DOE will hold a public meeting to allow for additional comment on this proposed rule. DOE will publish notice of any meeting in the **Federal Register**.

V. Procedural Issues and Regulatory Review

The regulatory reviews conducted for this proposed rule are identical to those conducted for the direct final rule published elsewhere in this issue of the **Federal Register**. Please see the direct final rule for further details.

A. 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 (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') 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 E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 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 the General Counsel's website (*www.energy.gov/gc/office-general-counsel*). DOE has not prepared an IRFA for the products that are the subject of this proposed rulemaking.

DOE 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 of this certification is set forth in the following paragraphs.

For manufacturers of consumer clothes dryers, the Small Business Administration (''SBA'') has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. (See 13 CFR part 121.) The size standards are listed by North American Industry Classification System (''NAICS'') code and industry description and are available at *www.sba.gov/document/support--table-size-standards.* Manufacturing of consumer clothes dryers is classified under NAICS 335220, ''Major Household Appliance Manufacturing.'' The SBA sets a threshold of 1,500 employees or fewer for an entity to be considered as a small business for this category.

To estimate the number of companies that could be small business manufacturers of consumer clothes dryers, DOE conducted a market survey using public information and subscription-based company reports to identify potential small business

manufacturers. DOE reviewed its Compliance Certification Database,[19] California Energy Commission's Modernized Appliance Efficiency Database System,[20] the ENERGY STAR Product Finder dataset,[21] individual company websites, import/export logs, and product specifications to create a list of companies that manufacture, produce, import, or private label the products covered by this rulemaking. DOE relied on public information and market research tools (*e.g.,* reports from Dun and Bradstreet [22]) to determine company structure, location, headcount, and annual revenue. DOE screened out companies that do not manufacture the products covered by this proposed rulemaking, do not meet the SBA's definition of a ''small business,'' or are foreign-owned and operated. DOE also asked stakeholders and industry representatives if they were aware of any small manufacturers during manufacturer interviews and through requests for comment.

DOE identified 19 OEMs of consumer clothes dryers. Of these 19 OEMs, DOE determined none of them qualify as a domestic ''small business manufacturer'' of consumer clothes dryers. Given the lack of small domestic OEMs with a direct compliance burden, DOE concludes that this proposed rule would not have ''a significant impact on a substantial number of small entities.''

DOE will transmit the 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).

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on February 29, 2024, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with 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 March 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons set forth in the preamble, DOE proposes to amend part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Amend § 430.32 by adding paragraph (h)(4) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(h) * * *

(4) Clothes dryers manufactured on or after March 1, 2028, shall have a combined energy factor, determined in accordance with appendix D2 of this subpart, no less than:

Product class	CEF_{D2} (lb/kWh)
(i) Electric, Standard (4.4 ft3 or greater capacity) *	3.93
(ii) Electric, Compact (120V) (less than 4.4 ft3 capacity)	4.33
(iii) Vented Electric, Compact (240V) (less than 4.4 ft3 capacity)	3.57
(iv) Vented Gas, Standard (4.4 ft3 or greater capacity)**	3.48
(v) Vented Gas, Compact (less than 4.4 ft3 capacity)	2.02
(vi) Ventless Electric, Compact (240V) (less than 4.4 ft3 capacity)	2.68
(vii) Ventless Electric, Combination Washer-Dryer	2.33

* The energy conservation standards in this product class do not apply to Vented Electric, Standard clothes dryers with a cycle time of less than 30 minutes, when tested according to appendix D2 in subpart B of this part.

** The energy conservation standards in this product class do not apply to Vented Gas, Standard clothes dryers with a cycle time of less than 30 minutes, when tested according to appendix D2 in subpart B of this part.

* * * * *

[FR Doc. 2024–04766 Filed 3–11–24; 8:45 am]

BILLING CODE 6450–01–P

[19] U.S. Department of Energy's Compliance Certification Database is available at *regulations.doe.gov/certification-data* (last accessed April 28, 2023).

[20] California Energy Commission's Modernized Appliance Efficiency Database System is available at *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx* (last accessed April 28, 2023).

[21] ENERGY STAR Product Finder is available at *www.energystar.gov/productfinder* (last accessed April 28, 2023).

[22] The Dun & Bradstreet subscription login is available at *app.dnbhoovers.com* (last accessed June 8, 2023).

FEDERAL REGISTER

Vol. 89 Tuesday,
No. 49 March 12, 2024

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 500, 501, et al.
Labeling Requirements for Approved or Conditionally Approved New Animal Drugs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 500, 501, 510, 514, and 516

[Docket No. FDA–2023–N–5160]

RIN 0910–AI43

Labeling Requirements for Approved or Conditionally Approved New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the requirements for the content and format of labeling for approved or conditionally approved new animal drugs to provide for a more comprehensive set of requirements in one location in the Code of the **Federal Register** (CFR). As part of this revision, certain current requirements would be updated and moved, and certain obsolete requirements would be removed. The proposed requirements would apply to the labeling of prescription and over-the-counter (OTC) new animal drugs, as well as new animal drugs for use in animal feeds.

DATES: Either electronic or written comments on the proposed rule must be submitted by June 10, 2024. Submit written comments (including recommendations) on information collection issues under the Paperwork Reduction Act of 1995 by April 11, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 10, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–5160 for ''Labeling Requirements for Approved or Conditionally Approved New Animal Drugs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words are required by the ''Providing Accountability Through Transparency Act,'' 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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) *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 title of this proposed collection is ''Labeling Requirements for Approved or Conditionally Approved New Animal Drugs.''

FOR FURTHER INFORMATION CONTACT:

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I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

FDA proposes to revise the existing regulations regarding the content and format of labeling for approved or conditionally approved new animal drugs. These proposed regulations would apply to the labeling of prescription and OTC new animal drugs, as well as new animal drugs for use in animal feeds. Certain existing regulations regarding the labeling of new animal drugs would be updated and moved from their current location and incorporated into the proposed regulations, including a new subpart H in part 201 (21 CFR part 201). FDA also proposes to amend or remove certain current regulations to ensure consistency with the proposed regulations.

Proposed subpart H would not apply to heritable intentional genomic alterations in animals. Proposed subpart H would also not apply to labeling of indexed legally marketed unapproved new animal drugs for minor species. In addition, proposed subpart H would not apply to promotional labeling or advertising.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would revise the existing requirements for the content and format of labeling for approved or conditionally approved new animal drugs. If finalized, sponsors of these new animal drugs would need to comply with these proposed regulations on a staggered schedule, over the course of 6 years, according to a schedule based on application number, with approved NADAs with higher application numbers having the earliest compliance date because they are more recently approved and therefore likely to need the fewest labeling revisions.

If finalized, this rule would enable FDA to provide sponsors with predictable requirements for the content and format of labeling for new animal drugs and codify FDA's longstanding practices with respect to the review of labeling submitted as part of a new animal drug application (NADA), certain abbreviated new animal drug applications (ANADAs) that reference a new animal drug for which the NADA has been withdrawn, or a new animal drug application for conditional approval (CNADA).

Currently a comprehensive set of regulations establishing labeling requirements for the content and format of labeling for new animal drugs does not exist in the CFR. These proposed regulations would provide sponsors with predictable requirements for the content and format of labeling for new animal drugs. Also, these proposed regulations would help sponsors more efficiently prepare labeling for new animal drugs to be submitted as part of an NADA, CNADA, or certain ANADAs by providing clear and consistent requirements for the information that would need to be included on each component of labeling for a new animal drug, as well as the format in which the information is to be presented.

FDA is proposing specific requirements for content and format of the labeling for approved or conditionally approved prescription and OTC new animal drugs, as well as approved or conditionally approved new animal drugs for use in animal feeds.

The proposed regulations would provide the following:

- The content and format of labeling components applicable to approved or conditionally approved new animal drugs.
- Definitions of labeling terms for approved or conditionally approved new animal drugs.
- A schedule for sponsors of approved or conditionally approved and marketed new animal drugs to comply with these proposed regulations within a maximum of 6 years from the effective date of any final rule.
- Provisions for foreign language translation of the labeling for approved or conditionally approved new animal drugs.
- A process for sponsors of new animal drugs to request exemptions from the proposed labeling requirements.
- Consolidation of the labeling requirements for the content and format of labeling for approved or conditionally approved new animal drugs into one section of the regulations. At present, existing requirements are dispersed throughout the regulations.

C. Legal Authority

FDA's revisions to the content and format requirements for animal drug labeling are authorized by various provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The premarket approval provisions of the FD&C Act authorize FDA to require that new animal drug labeling provide adequate information to permit safe and effective use of the drug.

The FD&C Act requires certain information be included on a drug's label and provides for certain exemptions from these requirements. Also, the FD&C Act authorizes FDA to establish additional exemptions by regulation.

The FD&C Act requires that new animal drug applications include specimens of the labeling proposed to be used for the drug. A new animal drug will be deemed unsafe if its labeling fails to conform to the approved labeling in the applicable approved new animal drug application, conditionally approved new animal drug application, or new animal drug index listing. Unsafe drugs are deemed adulterated under the provisions of the FD&C Act. The FD&C Act prohibits the marketing of drugs that are adulterated or misbranded as well as their adulteration or misbranding while in interstate commerce.

In addition to the other statutory provisions described above, the FD&C Act gives the FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

If this proposed rule is finalized, industry and FDA would incur cost savings from a reduction in the quantity and time burden of new animal drug labeling amendments and informal communications related to new animal drug labeling. There may be additional

benefits to users of approved or conditionally approved new animal drugs from greater predictability and ease of reading new animal drug labeling in the form of time saved searching for content, as well as benefits to animal or human health, which we are unable to quantify.

We expect that new animal drug sponsors would incur one-time costs to read and understand the rule, revise standard operating procedures (SOPs) related to labeling, and train employees on the revised SOPs. New animal drug sponsors would also bear costs to update labeling and prepare supplemental labeling applications to conform to the proposed requirements. FDA would incur costs to review these supplemental applications.

FDA estimates that the annualized benefits over 10 years would range from $0.143 million to $0.243 million at a 2 percent discount rate, with a primary estimate of $0.193 million. The annualized costs would range from $2.16 million to $2.77 million at a 2 percent discount rate, with a primary estimate of $2.45 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ADAA	Animal Drug Availability Act.
ANADA	Abbreviated New Animal Drug Application
CFR	Code of Federal Regulations.
CNADA	Conditionally Approved New Animal Drug Application.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FR	Federal Register.
HHS	Health and Human Services.
INAD	Investigational New Animal Drug.
MUMS	Minor Use Minor Species.
NADA	New Animal Drug Application.
NDC	National Drug Code.
NEPA	National Environmental Policy Act.
OMB	Office of Management and Budget.
OTC	Over-the-counter.
PCBs	Polychlorinated biphenyls.
PRA	Paperwork Reduction Act of 1995.
RLNAD	Reference-Listed New Animal Drug.
Rx	Prescription.
U.S.	United States.
U.S.C.	United States Code.
VFD	Veterinary Feed Directive.
VMF	Veterinary Master File.

III. Background

A. Introduction

In accordance with the definition in section 201(k) of the FD&C Act (21 U.S.C. 321(k)) the ''label'' is a display of written, printed, or graphic matter upon the immediate container of any article. Under section 201(m) of the FD&C Act, the term ''labeling'' means ''all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.'' Labeling, therefore, includes the label of any article, including new animal drugs.

Under existing regulations, proposed labeling must be included as part of an application filed with FDA for approval of a new animal drug, in accordance with section 512(b)(1)(F) of the FD&C Act (21 U.S.C. 360b(b)(1)(F)). Labeling for nonprescription, known as over-the-counter (OTC), new animal drugs should include adequate directions for use by the layperson under all conditions of use for which the new animal drug is intended, recommended, or suggested in any of the labeling or advertising sponsored by the applicant (see § 514.1(b)(3)(ii) (21 CFR 514.1(b)(3)(ii)). Labeling for prescription new animal drugs should bear adequate information for use under which veterinarians can use the new animal drug safely and for the purposes for which it is intended, including those purposes for which it is to be advertised or represented, in accordance with § 201.105 (21 CFR 201.105) (see § 514.1(b)(3)(iii)). All labeling for prescription or OTC new animal drugs must provide any necessary use restrictions prominently and conspicuously displayed (see § 514.1(b)(3)(iv)).

Labeling for new animal drugs intended for use in the manufacture of medicated feeds must include: (1) specimens of labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested in any of the labeling, including advertising, sponsored by the applicant; and (2) representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug (see § 514.1(b)(3)(v)). Sponsors of new animal drug applications commit to providing labeling for the new animal drug that prescribes, recommends, or suggests its use only under the conditions stated in the labeling included as part of the application (see § 514.1(b)(11)). All representations of labeling in the application apply to the new animal drug produced until changes are made in conformity with § 514.8 (21 CFR 514.8) (see § 514.1(b)(11)).

Sponsors of new animal drug applications may submit draft labeling for FDA's preliminary consideration of an application (see § 514.1(b)(3)(vi)). For example, sponsors sometimes include draft labeling content pertinent to key components of an application that are submitted for preliminary FDA review (*e.g.,* manufacturing components and composition, evidence to establish safety and effectiveness, and environmental assessment).

Under section 502(a)(1) of the FD&C Act (21 U.S.C. 352(a)(1)), a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular. A new animal drug for which an approval or conditional approval is in effect will be considered unsafe if its labeling fails to conform to the approved or conditionally approved application (section 512(a)(1)(A) and (B) of the FD&C Act).

B. Need for the Regulation

Based on FDA's experience in reviewing labeling for approved or conditionally approved prescription new animal drugs and informal feedback from sponsors of such new animal drugs in the past 60 years, it has become clear that sponsors would benefit from having more detailed requirements on the content, format, and order of information on labeling so that they can efficiently prepare adequate labeling for approved or conditionally approved prescription new animal drugs to be submitted as part of an NADA, CNADA, or certain ANADAs that reference a new animal drug for which the NADA has been withdrawn.

For example, existing § 201.105(c) provides requirements for labeling ''on or within the package'' from which prescription animal drugs are dispensed, and paragraph (d) of that section provides requirements for all labeling for prescription new animal drugs. Labeling for prescription new animal drugs typically consists of multiple components, such as the label, one or more package inserts, secondary container labeling, multiple unit carton labeling, shipping labeling, and/or display carton labeling. However, neither paragraph (c) nor (d) of § 201.105 provides direction on the format or order of information with respect to specific labeling components. Furthermore, it is not clear whether the information required by paragraph (d) of § 201.105 needs to be presented on all components of labeling for prescription new animal drugs, or if not, what critical information needs to be provided on specific labeling components, particularly smaller components of limited size.

Whereas existing § 201.105 provides at least some requirements for the content of labeling for prescription new animal drugs, there are currently no regulations that provide requirements for the general content and format of labeling for OTC new animal drugs and new animal drugs administered in animal feeds.

The lack of direction regarding format and content for each component of labeling has resulted in confusion for sponsors as they prepare labeling for FDA's review and sometimes results in poor quality labeling submissions. Poor quality labeling submissions increase the time needed by sponsors to revise and resubmit adequate labeling, and they increase time needed by FDA to review and approve labeling, and consequently, the application.

New animal drug labeling that presents information in an inconsistent manner can contribute to medication errors by making it difficult for veterinarians and animal owners to readily locate and understand critical directions and safety information. Information in the labeling for approved or conditionally approved new animal drugs presented in a consistent manner communicates information that is important to the safe use of a new animal drug in the medication use process (*i.e.,* from prescription, to procurement, preparation, and dispensing and administration of the medication to the animal).

Other regulations specifically pertaining to the labeling of certain new animal drugs include § 500.25 (21 CFR 500.25), ''Anthelmintic drugs for use in animals,'' § 500.55 (21 CFR 500.55), ''Exemption from certain drug-labeling requirements,'' § 510.105 (21 CFR 510.105), ''Labeling of drugs for use in milk-producing animals,'' § 510.106 (21 CFR 510.106), ''Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals,'' and § 510.410 (21 CFR 510.410), ''Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.''

The proposed rule would locate the labeling requirements for ''Anthelmintic drugs for use in animals,'' currently in § 500.25, with other labeling requirements for new animal drugs.

The proposed rule would remove the exemption in § 500.55, ''Exemption from certain drug-labeling requirements,'' because we believe that full disclosure labeling is needed for all prescription new animal drugs to ensure veterinarians are able to use these products safely and effectively.

In addition, the proposed rule would remove the labeling requirements in § 510.105, ''Labeling of drugs for use in milk-producing animals,'' and § 510.106, ''Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.'' The labeling requirements in these regulations do not provide adequate flexibility for targeted and informative statements with respect to human food safety warnings, including milk discard times, withdrawal periods, and residue warning statements for the labeling of new animal drugs intended for use in milk-producing animals.

Section 510.410, ''Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements,'' contains background information and warning and labeling requirements for this category of new animal drugs. We propose a conforming amendment to remove § 510.410 and to move portions of that section to be located with the other labeling requirements for new animal drugs.

C. FDA's Current Regulatory Framework

Current § 201.105 provides conditions that must be met for exempting prescription animal drugs from section 502(f)(1) of the FD&C Act, which requires the labeling to bear adequate directions for use. Section 201.105(b) requires the following information to appear on the label for prescription animal drugs for such products to be exempt from section 502(f)(1) of the FD&C Act:

- a standard statement restricting use to or on the order of a licensed veterinarian,
- dosage,
- route of administration if it is not oral,
- quantity or proportion of each active ingredient as well as information required, in accordance with section 502(e) of the FD&C Act,
- names of inactive ingredients if the drug is for other than oral use (with some exemptions), and
- an identifying lot or control number.

For containers too small or otherwise unable to fit a label with enough space to display all the required information, § 201.105(b) allows eliminating some information from these labels and placing it on other approved labeling.

Labeling for prescription new animal drugs must bear adequate information for use, including indications, effects, dosages, routes, methods, and frequency and duration of administration; any relevant warnings, hazards, contraindications, side effects, and precautions under which veterinarians can use the drug safely and for the intended purposes; and ingredient information as required for the label (see § 201.105(c) through (e)). All prescription animal drug labeling, except for labels and cartons, must bear the issuance dates of the latest revisions of such labeling (see § 201.105(e)). Applicants may submit a written request to the Commissioner of Food and Drugs for an exemption from inclusion of adequate information for use required in § 201.105(c)(1) from the dispensing package of prescription new animal drugs for which directions, hazards, warnings, and use information are commonly known to licensed veterinarians (see § 201.105(c)(2)).

A prescription drug intended for both human and veterinary use must comply with paragraphs (e) and (f) of § 201.105, in addition to § 201.100, which provides

requirements for prescription drugs for human use (see § 201.105(f)).

D. History of the Rulemaking

In 1955, FDA issued regulations at § 1.106(c) establishing requirements primarily for the label of prescription animal drugs (20 FR 9525 at 9533, December 20, 1955). The initial requirements were expanded in 1960 to cover the labeling of such drugs more fully (25 FR 12592, December 9, 1960). As part of FDA's reorganization of its regulations, in 1975 § 1.106(c) was redesignated as § 201.105 (40 FR 13494 at 13496, March 27, 1975). Most provisions in current § 201.105 are similar to the 1960 version of § 1.106(c).

IV. Legal Authority

FDA's revisions to the content and format requirements for animal drug labeling are authorized by various provisions of the FD&C Act, including sections 201, 301, 501, 502, 503, 504, 512, 571, and 701 (21 U.S.C. 321, 331, 351, 352, 353, 354, 360b, 360ccc, and 371). Section 201 contains definitions relevant to the proposed content and format requirements, including for the terms ''label'' and ''labeling''. Pursuant to section 201(k) of the FD&C Act, the term ''label'' means ''a display of written, printed, or graphic matter upon the immediate container of any article.'' That provision requires that any words, statements, or other information appearing on the label also appear on the outside container or wrapper of the retail package, or be easily legible through the outside container or wrapper. Section 201(m) of the FD&C Act defines ''labeling'' to mean ''all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.''

Section 301 of the FD&C Act prohibits the marketing of drugs that are adulterated or misbranded as well as their adulteration or misbranding while in interstate commerce. Section 501(a)(5) of the FD&C Act deems a new animal drug to be adulterated if it is unsafe within the meaning of section 512 of the FD&C Act. Under section 512 of the FD&C Act, a new animal drug will be deemed unsafe if its labeling fails to conform to the applicable approved application under section 512 of the FD&C Act, conditionally approved application under section 571 of the FD&C Act, or index listing under section 572 of the FD&C Act (21 U.S.C. 360ccc-1).

Section 502 of the FD&C Act specifies conditions that cause a drug to be misbranded. Under section 502(a) of the FD&C Act, a drug is deemed to be misbranded if its labeling is false or misleading ''in any particular.'' Section 201(n) of the FD&C Act deems a product's labeling misleading if it fails to reveal facts regarding the consequences that may result from using the article under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. Under section 502(b) of the FD&C Act, a drug in package form is deemed to be misbranded unless its label bears the name and place of business of the manufacturer, packer, or distributor, and it contains an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Section 502(c) of the FD&C Act, deems a drug misbranded if any word, statement, or other information required by law or regulation to be included on the label or labeling does not appear with such prominence and conspicuousness, and in such terms, that it is likely to be read and understood by ordinary individuals under customary conditions of purchase and use.

Section 502(e) of the FD&C Act specifies requirements for including the established name of the drug and for listing the active and inactive ingredients on the drug's label. It also provides for certain exemptions from the requirement to list active and inactive ingredients and authorizes the Secretary to establish additional exemptions from some of the requirements in section 502(e) by promulgating regulations where compliance would be impracticable.

Section 502(f) of the FD&C Act deems a drug to be misbranded if its labeling lacks adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

Section 502(j) of the FD&C Act deems a drug to be misbranded if it is dangerous to health when used in the dosage or manner, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

Under section 502(w)(1) of the FD&C Act, a new animal drug that has been conditionally approved is deemed to be misbranded if its labeling fails to conform with the approved application or fails to include the labeling information required under section 571(f) of the FD&C Act. Section 571(f) requires the label and labeling of a new animal drug with a conditional approval to contain the statement ''conditionally approved by FDA pending a full demonstration of effectiveness under application number,'' in addition to other information as required by the Secretary. Effective September 30, 2023, section 502(w)(3) requires the labeling of new animal drugs that have received approval under section 512 of the FD&C Act to include the application number in the format ''Approved by FDA under (A)NADA # xxx-xxx.''

Section 503(f) of the FD&C Act provides certain labeling requirements specific to prescription animal drugs, including a required cautionary statement. Section 503(f)(2) exempts prescription animal drugs from having to comply with some of the requirements in section 502 of the FD&C Act, including the requirement for there to be adequate directions for use (section 502(f)), provided certain dispensing and labeling requirements specified in section 503(f) are met.

Section 504 of the FD&C Act authorizes the Secretary to issue regulations specific to veterinary feed directive (VFD) drugs for use in or on animal feed, including regulations prescribing a cautionary statement and other information to be included on the labeling of VFD drugs and animal feed containing such drugs. Under section 504(b), VFD drugs and feed containing such drugs will be deemed to be misbranded if their labeling fails to include such required information.

In addition, the premarket approval provisions of the FD&C Act authorize FDA to require that animal drug labeling provide adequate information to permit safe and effective use of the drug. Under section 512 of the FD&C Act, FDA will approve a NADA only if the drug is shown to be both safe and effective under the conditions of use set forth in the drug's labeling. Under section 571 of the FD&C Act, FDA will conditionally approve a new animal drug application (CNADA) only if the drug is shown to be safe, and there is a reasonable expectation of effectiveness for use, under the conditions of use set forth in the drug's labeling. Section 512(b)(1)(F) of the FD&C Act requires that the application for approval of a new animal drug include specimens of the labeling proposed to be used for the drug. A new animal drug that has been approved or conditionally approved by FDA will be deemed to be unsafe (and therefore adulterated under section 501(a)(5) of the FD&C Act) if its labeling does not conform to its approved application.

In addition to the other statutory provisions described above, section 701(a) of the FD&C Act gives the Secretary general rulemaking authority

to issue regulations for the efficient enforcement of the FD&C Act.

FDA has previously issued implementing regulations governing the format and content of labeling for animal drugs. This proposed rule, when finalized, would revise the content and format of labeling requirements applicable to approved and conditionally approved new animal drugs and would consolidate these requirements in subpart H of part 201.

V. Description of the Proposed Rule

FDA proposes to add subpart H to part 201 (hereafter called proposed subpart H) to revise the existing requirements for the content and format of labeling for approved or conditionally approved new animal drugs. Proposed subpart H would be titled ''Labeling Requirements for Approved or Conditionally Approved New Animal Drugs'' and would apply to new animal drugs that are approved under section 512 of the FD&C Act or conditionally approved under section 571 of the FD&C Act. These regulations would not apply to legally marketed unapproved new animal drugs for minor species that are indexed in accordance with section 572 of the FD&C Act. These regulations would not apply to the labeling of heritable intentional genomic alterations in animals, or to promotional labeling or advertising.

Sponsors of approved or conditionally approved and marketed new animal drugs would need to comply with these requirements per the schedule in proposed § 201.404(a)(4), (b), (c), or (d). Consistent with current practice, we expect that sponsors of new animal drugs that are the subject of an ANADA approved or submitted pursuant to section 512(n) of the FD&C Act (*i.e.,* a generic new animal drug) will submit a supplemental application to their ANADA to conform the labeling of their generic new animal drugs with the revised labeling of the reference-listed new animal drug (RLNAD). Therefore, in the preliminary regulatory impact analysis we examine the costs and benefits of these requirements for ANADAs that reference an NADA that has not been withdrawn. However, for generic new animal drugs that are the subject of an ANADA that reference a new animal drug for which the NADA has been voluntarily withdrawn for reasons other than safety or effectiveness, or that reference a new animal drug for which the NADA that has been withdrawn on the basis of one or more of the grounds included under section 512(e) of FD&C Act and for which the ANADA's approval was not affected by the withdrawal, labeling for such ANADAs would need to comply with proposed subpart H per the proposed schedule described in proposed § 201.404(a)(4)(iii).

The proposed requirements are based on FDA's experience in reviewing labeling submitted for the approval or conditional approval of new animal drugs and its experience in implementing existing regulations for labeling of new animal drugs, as well as input received from new animal drug sponsors, end users of animal drugs, information collected from post approval surveillance, and other stakeholders. We intend for these proposed regulations to provide consistent formatting of new animal drug labeling by identifying the specific labeling components that would be required and permitted for each new animal drug, the information needed for each component, and the order in which information would appear on labeling. Consistent and standardized content and format of new animal drug labeling may make it easier for end users (veterinarians, animal owners, or persons treating the animals) to access, read, and use the information to make informed decisions quickly, while promoting safe use of the drug. Such labeling may contribute to reducing medication errors.

Providing clear and consistent requirements in these proposed regulations should help to reduce the amount of time needed by sponsors of new animal drugs to prepare high quality proposed labeling for their new animal drugs. The submission of higher quality proposed labeling by sponsors of new animal drugs may reduce the amount of time needed by FDA to review and approve labeling, and consequently, the new animal drug application.

We include the following eight sections in proposed subpart H:

- § 201.401 Scope.
- § 201.403 Definitions.
- § 201.404 General requirements.
- § 201.405 Content and format for prescription new animal drug labeling.
- § 201.407 Content and format for OTC new animal drug labeling.
- § 201.409 Content and format of labeling for new animal drugs for use in animal feeds.
- § 201.411 Exemptions from labeling requirements for approved or conditionally approved new animal drugs.
- § 201.413 Labeling requirements for certain approved or conditionally approved new animal drugs.

A. Scope (Proposed § 201.401)

The proposed rule would revise the existing requirements for the content and format of labeling for prescription (Rx) new animal drugs, OTC new animal drugs other than those for use in animal feeds in accordance with part 558 (21 CFR part 558), and new animal drugs for use in animal feeds that are subject to part 558, including VFD drugs, that are subject of the specific applications identified in proposed § 201.401(a)(1) through (4).

Subpart H would apply to the labeling of new animal drugs that are the subject of an NADA approved or submitted pursuant to section 512 of the FD&C Act (see proposed § 201.401(a)(1)), new animal drugs that are the subject of a CNADA conditionally approved or submitted pursuant to section 571 of the FD&C Act (see proposed § 201.401(a)(2)), and new animal drugs that are the subject of an ANADA approved or submitted pursuant to section 512(n) of the FD&C Act (*i.e.,* a generic new animal drug) that reference a new animal drug for which the NADA has been voluntarily withdrawn for reasons other than safety or effectiveness, or that reference a new animal drug for which the NADA has been withdrawn on the basis of one or more of the grounds included under section 512(e) of the FD&C Act and for which the generic new animal drug's approval was not affected by the withdrawal (see proposed § 201.401(a)(3)).

For some proprietary Type B or Type C medicated feeds, the formulation and labeling are approved and maintained in an NADA or CNADA file. In other situations, the underlying data and labeling for the proprietary Type B or Type C medicated feed to support the approved uses are maintained in a Veterinary Master File (VMF). The latter would include, as an example, situations in which a proprietary Type B or Type C medicated feed is manufactured via modification to an approved formulation published in the CFR or where a feed manufacturer creates its own proprietary formulation. The labeling of these proprietary medicated feeds is maintained in a VMF and would be required to comply with proposed subpart H (see proposed § 201.401(a)(4)).

The proposed requirements would apply to the applications described in proposed § 201.401(a)(1) through (4) for new animal drugs that are approved before the effective date of any final rule based on this proposed rule, pending on the effective date of any final rule based on this proposed rule, or submitted on

or after the effective date of any final rule based on this proposed rule (see proposed § 201.401(c)). The schedule for compliance is provided in proposed § 201.404(a)(4).

The proposed requirements would deem any approved or conditionally approved new animal drug subject to this subpart that does not fully comply with the applicable requirements in accordance with the schedule proposed in § 201.404(a)(4) to be misbranded under section 502 of the FD&C Act and, if that drug is a VFD drug, also under section 504(b) of the FD&C Act (see proposed § 201.401(c)).

The proposed requirements would not apply to the labeling of legally marketed unapproved new animal drugs for minor species that are indexed in accordance with section 572 of the FD&C Act (see proposed § 201.401(d)(1)) or to the labeling of heritable intentional genomic alterations in animals (see proposed § 201.401(d)(2)).

The proposed requirements would not apply to promotional labeling or advertising (see proposed § 201.401(d)(3)). Promotional labeling for new animal drugs is generally any labeling other than labeling required in an application for a new animal drug (see § 514.1(b)(3)). Materials that may be considered promotional labeling or advertising include, for example, brochures, booklets, mailing pieces, or reminder labeling. These materials are described in more detail for prescription human drugs and prescription new animal drugs in existing 21 CFR 202.1.

B. Definitions (Proposed § 201.403)

Proposed § 201.403 would establish definitions for terms used in proposed subpart H.

The proposed definitions for the following terms would be the same as those already in the FD&C Act or elsewhere in the regulations:

- ''active ingredient''
- ''adverse drug experience''
- ''ANADA''
- ''drug product''
- ''established name''
- ''extralabel use''
- ''free-choice medicated feed''
- ''inactive ingredient''
- ''label''
- ''labeling''
- ''lot number''
- ''control number''
- ''batch number''
- ''NADA''
- ''new animal drug''
- ''sponsor''
- ''strength''
- ''Type A medicated article''
- ''Type B medicated feed''
- ''Type C medicated feed''
- ''veterinary feed directive (VFD)''
- ''VFD drug''

We would base the definition of ''full prescribing information'' for prescription new animal drugs on the requirements for full prescribing information for prescription human drugs and biologics established in § 201.57(c) (21 CFR 201.57(c)).

For OTC new animal drugs, we would create a similar term, called ''full product information.'' We would define ''full product information'' as all information necessary for the safe and effective use of an OTC new animal drug.

We would base the definitions of other terms on the requirements established in § 201.57(c) for full prescribing information of prescription human drugs and biologics. These terms include ''adverse reaction,'' ''boxed warning,'' and ''contraindication.'' The proposed definition of ''precaution'' would be based on the requirements for the ''Other special care precautions'' labeling section described in § 201.57(c)(6)(ii). The proposed definition of ''warning'' would be based on general requirements for the ''Warnings and Precautions'' section described in § 201.57(c)(6)(i).

We would define ''active moiety'' as the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

We would define ''field study'' as a type of adequate and well-controlled study designed to assess the effectiveness and/or safety of a new animal drug in the target animal under conditions that closely approximate the actual conditions of use.

The term ''indication'' would mean ''the use for which the new animal drug is approved or conditionally approved.''

We would define ''milk discard time'' as the interval between the time of the last administration of a new animal drug and the time when the milk can be safely consumed.

We would define ''residue warning statement'' as a statement that warns against the use of the new animal drug in animals for which the withdrawal period and/or milk discard time has not been determined, and/or provides other information to prevent illegal drug residues in food products from animals treated with the new animal drug.

The term ''target animal'' would mean the species, or collection of species, of animals, and if applicable, the specific subset(s) of animals (*e.g.,* life stage, production class, age, gender) for which the new animal drug is approved or conditionally approved. Particularly for food-producing animals, new animal drugs may be approved for use only during a specific life stage (*e.g.,* growing, pregnant, lactating), production class (*e.g.,* growing beef steers and heifers fed in confinement for slaughter, broiler chickens, finishing pigs), age, or gender of the animal.

We would define ''environmental warning'' as a warning that identifies any potential hazard to the human environment associated with the use of the new animal drug. We would define ''user safety warning'' as a warning that identifies any serious adverse reaction or potential hazard to human health associated with human exposure during use of a new animal drug via contact, inhalation, ingestion, injection, or by other means.

The term ''withdrawal period'' would mean the interval between the time of the last administration of a new animal drug and the time when the animal can be safely slaughtered for food.

The proposed regulations would provide definitions for terms associated with key labeling components for new animal drugs, including ''immediate container,'' ''package insert,'' ''secondary container,'' ''small label,'' ''shipping labeling,'' ''representative Type B medicated feed labeling,'' and ''representative Type C medicated feed labeling.''

C. General Requirements (Proposed § 201.404)

The proposed rule would require the labeling for approved or conditionally approved new animal drugs to conform to an application approved under section 512 of the FD&C Act or conditionally approved under section 571 of the FD&C Act (see proposed § 201.404(a)(1)).

The proposed rule would require the labeling to be informative and accurate and neither promotional in tone nor false or misleading in any particular and would require the labeling to be updated if new information becomes available to cause the labeling to become inaccurate, false, or misleading, in accordance with § 514.8 of this chapter (see proposed § 201.404(a)(2) and (3)).

The proposed rule would require labeling conforming to this subpart to be submitted to FDA per the earliest applicable compliance date provided in the schedule, unless § 201.404(b), (c), or (d) was applicable (see proposed § 201.404(a)(4)). See also section VI for

discussion of Proposed Effective/Compliance Dates.

Labeling included in NADAs, CNADAs, or supplements to NADAs or CNADAs subject to § 514.8(c)(2) that are submitted to FDA for approval more than 180 days after the effective date of any final rule based on this proposed rule would be required to conform to the regulations as part of the application (see proposed § 201.404(a)(4)(i)).

The proposed rule would require sponsors with NADAs, CNADAs, or supplements to NADAs or CNADAs subject to § 514.8(c)(2) that are pending with FDA on the effective date of any final rule based on this proposed rule, or submitted within 180 days after the effective date of any final rule based on this proposed rule, to submit conforming labeling as part of the application or supplemental application, or alternatively, as a supplement to the approved application or supplemental application within 180 days after the approval date of the application or supplemental application, as determined by FDA (see proposed § 201.404(a)(4)(ii)).

The proposed rule would establish a timeline for submission of supplements with conforming labeling for marketed new animal drugs originally approved before the effective date of any final rule based on this proposed rule, based on NADA number (see proposed § 201.404(a)(4)(iii) through (vii)).

For an ANADA that references a new animal drug for which the NADA has been voluntarily withdrawn for reasons other than safety or effectiveness, or that references a new animal drug for which the NADA has been withdrawn on the basis of one or more grounds included under section 512(e) of the FD&C Act and the ANADA's approval was not affected by the withdrawal, the labeling for such an ANADA would be required to be submitted between the [effective date of a final rule plus 1 year] and the [effective date of a final rule plus 2 years] (see proposed § 201.404(a)(4)(iii)). For an ANADA that references a new animal drug for which the NADA has not been withdrawn, consistent with current practice, we expect that the sponsor of such a generic new animal drug will submit a supplemental application to the ANADA to conform the labeling of the generic new animal drug with the revised labeling of the RLNAD once the labeling of the RLNAD has been revised in accordance with the schedule in proposed § 201.404.

Sponsors of proprietary Type B or Type C medicated feeds for which the underlying data and labeling are maintained in a VMF would be required to submit conforming labeling to the VMF within 180 days after all conforming labeling has been approved for the NADA or CNADA that is the approved or conditionally approved source of the new animal drug used to manufacture the proprietary medicated feed (see proposed § 201.404(b)).

The labeling for new animal drugs conditionally approved before the effective date of a final rule would not be required to comply with proposed subpart H until an application for full approval is submitted unless a supplement subject to § 514.8(c)(2) is submitted to the CNADA after the effective date of a final rule (see proposed § 201.404(c)). The conditional approval is valid for 1 year and can be renewed annually for up to a total of 5 years by the sponsor showing active progress towards demonstrating substantial evidence of effectiveness. The conditional approval will be terminated if substantial evidence of effectiveness is not demonstrated (section 571(d) of the FD&C Act).

The proposed rule would also establish an alternative schedule for submitting conforming labeling for combination new animal drugs intended for use in animal feed or drinking water and approved, on or before the effective date of a final rule, in accordance with section 512(d)(4) of the FD&C Act, *i.e.,* per the Animal Drug Availability Act (ADAA) of 1996. Section 512(d)(4) was amended as part of the Minor Use Minor Species (MUMS) Act of 2004 to clarify that only products approved under section 512(b)(1) of the FD&C Act can be used in ADAA combinations. Thus, ADAA combination new animal drugs exclude conditionally approved drugs subject to section 571 of the FD&C Act. These ADAA combination new animal drugs generally provide for more than one approved new animal drug (as a Type A medicated article) to be mixed into medicated feed or drinking water. These ADAA combination new animal drug approvals result in new representative (''Blue Bird'') labeling for medicated feeds containing the combination (see proposed § 201.409).

Representative labeling for medicated feed containing the approved combination of new animal drugs includes information from the approved labeling for the individual drugs. Thus, it would be appropriate that the labeling for individual drugs included in the combination be updated to conform to any final regulations before representative labeling for the feeds containing the combination approval is updated. However, the ADAA combination approval would occur after the individual drugs are approved; therefore, the NADA number for the combination approval would be higher than the NADA numbers for the individual new animal drugs. Thus, according to the schedule proposed in § 201.404(a)(4), the conforming labeling for a combination approval would likely need to be submitted before the conforming labeling for the individual drugs in the combination. To address this problem, the proposed rule would require the conforming labeling for the combination new animal drug to be submitted within 180 days of the approval of all conforming labeling for the individual new animal drugs used in the combination (see proposed § 201.404(d)).

The range of NADA numbers provided as ''breakpoints'' in the proposed schedule for the submission of conforming labeling are intended to provide for a relatively uniform number of labeling supplements during each 1-year interval. The schedule would require more recently approved new animal drugs to conform to the requirements first because they are more likely to be consistent with the new requirements than the labeling of older new animal drugs. Sponsors of older new animal drug applications would have a longer amount of time to comply with the new requirements. Table 1 provides these NADA ranges in the first column. Table 1 provides in the second column the number of currently approved and marketed NADAs within the ranges of NADAs calculated by FDA as of September 2023 and adjusts for ADAA combination new animal drugs that would need to conform after all individual new animal drugs in the combination have conformed (see proposed § 201.404(d)). The first row of the second column of table 1 includes ANADAs that reference a new animal drug for which the NADA has been voluntarily withdrawn for reasons other than safety or effectiveness, or that reference a new animal drug for which the NADA has been withdrawn on the basis of one or more of the grounds included under section 512(e) of FD&C Act and for which the ANADA's approval was not affected by the withdrawal. Table 1 also provides in the third column the number of currently approved and marketed ANADAs with a RLNAD that has not been withdrawn, as calculated by FDA as of September 2023; these ANADAs are included in the row that corresponds to the NADA number for the RLNAD.

TABLE 1—NUMBER OF AFFECTED APPLICATIONS AS OF SEPTEMBER 2023 [1]

NADA Nos.	NADA	ANADA with a RLNAD [2]	Total
N–141–300 +; certain ANADAs	[3] 104	9	113
N–141–000 to N–141–299	101	86	187
N–115–000 to N–140–999	105	87	192
N–045–000 to N–114–999	116	68	184
N–000–001 to N–044–999	86	66	152
Total	512	316	828

[1] These numbers will be updated in a final rule.
[2] These are ANADAs with a RLNAD that has not been withdrawn, and they are in the row that corresponds to the NADA number for the RLNAD.
[3] This number includes six ANADAs that reference a withdrawn NADA.

The proposed rule would provide direction for situations in which it may not be clear how a requirement in subpart H applies to a particular new animal drug, or whether it applies. FDA approves and conditionally approves new animal drugs for many species of animals. For some new animal drugs, certain sections or subsections of labeling required by proposed subpart H would not be applicable. For example, new animal drugs approved or conditionally approved for use in non-food-producing animals (*e.g.,* cats, dogs) would not require the labeling subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods''. As another example, certain new animal drugs may not have contraindications. We would make the final determination in these situations as to the applicability of requirements in subpart H to specific new animal drugs (see proposed § 201.404(e)).

In addition, some sections in subpart H propose different options to meet the labeling requirements. For example, proposed § 201.405(b) would provide various options for presenting the ''Indications for Use'' section on the label for a prescription new animal drug, depending on size of the label. In those situations where the most appropriate option is not clear, we would make the final determination (see proposed § 201.404(e)). Ordinarily, such determinations would be made during the review of the new animal drug and its labeling.

When sponsors would submit labeling for purposes of conforming to the requirements of proposed subpart H according to the schedule in proposed § 201.404(a)(4), the proposed rule would require all labeling components for an approved or conditionally approved new animal drug to be provided in one submission. FDA would refuse to file labeling submissions intended to conform to this subpart that are incomplete. This would ensure that the content and format is consistent across all the labeling components for a particular new animal drug. Also, this would enable FDA to review and compare all labeling components at the same time to ensure that they conform to the proposed regulations when finalized (see proposed § 201.404(f)).

The proposed rule would establish general requirements for the format of labeling of approved or conditionally approved new animal drugs in proposed § 201.404(g). The format and content of labeling for prescription new animal drugs, OTC new animal drugs, or new animal drugs for use in animal feeds would be required to comply with the general requirements in proposed § 201.404(g), as applicable, in addition to format and content specific requirements for each type of new animal drug (see proposed §§ 201.405, 201.407, or 201.409, respectively).

The proposed rule would establish requirements for the placement, size, and prominence of the established name relative to the proprietary name for approved or conditionally approved prescription new animal drugs in proposed § 201.404(g)(1). These requirements are in accordance with § 201.10(g)(1) and (2) (21 CFR 210.10(g)(1) and (2)) and section 502(e)(1)(B) of the FD&C Act.

The proposed rule would establish requirements for the placement, size, and prominence of the established name relative to the proprietary name of approved or conditionally approved OTC new animal drugs and labeling for approved or conditionally approved new animal drugs for use in animal feeds, excluding representative Type B and Type C medicated feed labeling (see proposed § 201.404(g)(2)).

The proposed rule would provide the requirements for the placement, size, and prominence of the established name on representative Type B and Type C medicated feed labeling for approved or conditionally approved new animal drugs for use in animal feeds (see proposed § 201.404(g)(3)).

The proposed rule would require labeling text to be easy to read and with letters that do not touch. For certain text on labeling for new animal drugs, we believe that black text on a white background and use of a single type style is the easiest to read. Accordingly, the proposed rule would require that the running text, section headings, and subsection headings of package inserts must be in black type and on a white background and use a single type style because package inserts provide full prescribing information for prescription new animal drugs and full product information for OTC new animal drugs. Black text on a white background also would be required for representative labeling for Type B and C medicated feeds. For all other labeling components for new animal drugs, other color combinations would be allowed, provided that there is sufficient contrast between text and the background colors to ensure readability. See proposed § 201.404(g)(4) and (5).

The proposed rule would establish requirements for presentation of graphics and designs on labeling for approved or conditionally approved new animal drugs (see proposed § 201.404(g)(6)). Representative labeling for Type B and C medicated feeds would not be permitted to have logos, graphics, or designs other than illustrations or tables that FDA determines are necessary for proper use of the medicated feed. This proposed format is consistent with the purpose of representative labeling for Type B and C medicated feeds for use as template labeling and is also consistent with the format of representative labeling for Type B and C medicated feeds currently used in the medicated feeds industry. The proposed rule would require the presentation of graphics and designs on other labeling components for approved or conditionally approved new animal drugs to comply with § 201.15(b)(1) (21

CFR 201.15(b)(1)) and proposed § 201.404(a)(2) (see proposed § 201.404(g)(6)). If graphics are incorporated into the background of these labeling components, for any text appearing over the graphics there would need to be sufficient contrast between the text and the graphics colors to ensure readability of the text. The use of compressed arrows on labeling would be limited to the subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods,'' in accordance with the requirements in proposed § 201.404(g)(8) (see proposed § 201.404(g)(6)).

The proposed rule would establish minimum letter height or type size requirements that would vary for each labeling component and ensure appropriate space on each component while maintaining readability of text (see proposed § 201.404(g)(7)).

Section headings and subsection headings would be required to be in bold type that prominently distinguishes them from other approved labeling information. Section headings would be required to be left justified or centered, whereas subsection headings would be required to be left justified. An exception would be the subsection of labeling entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods,'' in which the subsection heading, and the contents of the subsection, would be required to be centered within compressed arrows (see proposed § 201.404(g)(8)).

The proposed rule would require that, if the National Drug Code is included on labeling of new animal drugs, then it must appear in accordance with 21 CFR 207.33 (see proposed § 201.404(h)).

The proposed rule would require all words, statements, and other information on the labeling for approved or conditionally approved new animal drugs to appear in English. In addition, the proposed rule would also establish requirements for additional foreign language translations of new animal drug labeling (see proposed § 201.404(i)).

For approved or conditionally approved prescription new animal drugs, the proposed rule would require that if any section or wording of a labeling component is translated into a foreign language, the entire full prescribing information would also be required to be translated into the foreign language. In certain situations, FDA may also require additional wording on other labeling components for the prescription new animal drug to be translated into the foreign language. These requirements would ensure that all information necessary for the safe and effective use of the prescription new animal drug would be provided in the foreign language (see proposed § 201.404(i)(1)).

For approved or conditionally approved OTC new animal drugs, the proposed rule would require that if any section or wording of a labeling component is translated into a foreign language, the entire full product information would also be required to be translated into the foreign language. In certain situations, FDA may also require additional wording on other labeling components for the OTC new animal drug to be translated into the foreign language. These requirements would ensure that all information necessary for the safe and effective use of the OTC new animal drug would be provided in the foreign language (see proposed § 201.404(i)(2)).

For approved or conditionally approved new animal drugs for use in animal feeds, the proposed rule would require that if the labeling contains any representation in a foreign language, all labeling must also appear in the foreign language (see proposed § 201.404(i)(3)).

For all situations where labeling for new animal drugs is translated into a foreign language, the translated wording would be required to comply with the format and content requirements for prescription, OTC, or new animal drugs for use in animal feeds in proposed § 201.405(a), § 201.407(a), or § 201.409, respectively.

FDA may limit the number of languages into which labeling information is translated to ensure clarity of information and the safe and effective use of the new animal drug. This proposed limitation would avoid multipage labeling in multiple languages. We intend for this limitation to reduce medication errors and reduce the time needed to locate information on labeling (see proposed § 201.404(i)(4)).

The proposed rule would allow the predominant language to be substituted for English on the labeling for new animal drugs distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is other than English. We may determine that such new animal drugs may be altogether exempt from the requirements in proposed § 201.404(i) (see proposed § 201.404(j)).

D. Content and Format for Prescription (Rx) New Animal Drug Labeling—Overview (Proposed § 201.405)

The proposed rule provides content and format requirements for all components of labeling for approved or conditionally approved prescription (Rx) new animal drugs. Proposed § 201.405 would not apply to approved or conditionally approved new animal drugs intended for use in or on animal feed under the professional supervision of a licensed veterinarian because, in accordance with section 504(a) of the FD&C Act, such drugs are approved or conditionally approved as VFD drugs. Proposed § 201.409 would establish the content and format requirements for all components of labeling for approved or conditionally approved new animal drugs intended for use in animal feeds that are subject to part 558, including VFD drugs.

The proposed rule would require that labeling sections or subsections that do not apply be omitted from the labeling for approved or conditionally approved Rx new animal drugs (see proposed § 201.405). For example, Rx new animal drugs approved or conditionally approved for use in non-food-producing animals (*e.g.,* cats, dogs) would not require the labeling subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods''.

FDA determines the final content of each applicable section of labeling during the review of each new animal drug as part of the approval process.

Full prescribing information for Rx new animal drugs would include all information necessary for safe and effective use of the Rx new animal drug. Thus, all approved or conditionally approved Rx new animal drugs would be required to provide a labeling component that includes full prescribing information. The proposed rule would identify the information that would be required to be included on the labeling component that would provide full prescribing information for Rx new animal drugs. If a package insert is provided with an Rx new animal drug, the proposed rule would require the package insert to include full prescribing information. If only partial information is provided on a package insert, the user may mistakenly assume the package insert includes complete information on the safe and effective use of the drug when in fact it does not. If no package insert is provided with an Rx new animal drug, the secondary container labeling would be required to include full prescribing information (see proposed § 201.405(a)).

The label is the labeling component that appears on the immediate container, which is the container in contact with the drug. The proposed rule would establish content and format requirements for the label for an approved or conditionally approved Rx new animal drug (see proposed § 201.405(b)) and for a small label for an

approved or conditionally approved Rx new animal drug that FDA determines lacks sufficient space to comply with proposed § 201.405(b) (see proposed § 201.405(c)).

For purposes of proposed subpart H, the proposed rule would define a package insert for an approved or conditionally approved Rx new animal drug as a labeling component that contains full prescribing information and is included with the immediate container or secondary container or is attached to the label (see proposed § 201.403). Where the package insert is attached to the label, which is sometimes referred to as, for example, ''extended labeling,'' ''onserts,'' or ''outserts,'' for purposes of proposed subpart H, the package insert providing full prescribing information and attached to the label would need to comply with proposed § 201.405(a). The label would need to comply with proposed § 201.405(b) or (c), as applicable.

FDA considers the secondary container for a new animal drug to be the packaging that surrounds the immediate container. The proposed rule would establish content and format requirements for secondary container labeling for an approved or conditionally approved Rx new animal drug (see proposed § 201.405(d)). If a package insert is provided with an Rx new animal drug, then the secondary container labeling would be required to comply with proposed § 201.405(d), and the package insert would be required to provide full prescribing information to comply with proposed § 201.405(a). If no package insert is provided with an Rx new animal drug, the proposed rule would require full prescribing information to appear on the secondary container labeling (see proposed § 201.405(a)).

In accordance with the definition of ''label'' in section 201(k) of the FD&C Act, information on the label must also appear on an outside container or wrapper of the retail package, if it exists, or be easily legible through the outside container or wrapper. For purposes of these proposed regulations, FDA considers the secondary container to be an ''outside container or wrapper of the retail package'' for new animal drugs. Therefore, if a secondary container exists, the proposed rule would require the secondary container labeling to include all information that would be on the label in accordance with proposed § 201.405(b) or (c), unless the information on the label is easily legible through the secondary container (see proposed § 201.405(a) and (d)).

Shipping labeling is associated with the outermost carton containing a new animal drug, which is intended for shipping, but not displaying the product. The proposed rule would establish content and format requirements for the shipping labeling of approved or conditionally approved Rx new animal drugs, including a requirement that such shipping labeling identify the new animal drug, the manufacturer, and drug storage and handling information. However, approved or conditionally approved Rx new animal drugs that are controlled substances would not include information that identifies the drug, in accordance with § 1301.74(e) (21 CFR 1301.74(e)), to guard against storage or in-transit losses (see proposed § 201.405(e)).

Depending on how a sponsor intends to sell or display an approved or conditionally approved Rx new animal drug, there may be other containers such as display cartons and multiple unit (multi-unit) cartons that contain immediate containers or secondary containers. These containers may be packaged in shipping cartons. The proposed rule would establish content and format requirements for the labeling of these other containers for Rx new animal drugs (see proposed § 201.405(f)).

Labeling sections and subsections for Rx new animal drugs would not be numbered. Headings of sections and subsections that would be required to appear verbatim on labeling are identified in the proposed regulations in quotations. Similarly, certain other labeling text would be required to appear verbatim on labeling; this text is also identified in the proposed regulations in quotations.

The proposed rule would require the labeling of approved or conditionally approved Rx new animal drugs to comply with other applicable requirements in proposed subpart H (see proposed § 201.405).

1. Labeling Providing Full Prescribing Information (Proposed § 201.405(a))

FDA uses the term ''full prescribing information'' to identify all information necessary for the safe and effective use of approved or conditionally approved Rx new animal drugs. The proposed rule would establish content and format requirements for the component of labeling that provides full prescribing information for approved or conditionally approved Rx new animal drugs (see proposed § 201.405(a)).

If a package insert is provided with an approved or conditionally approved Rx new animal drug, the proposed rule would require the package insert to include full prescribing information (see proposed § 201.405(a)). If a package insert is provided with an approved or conditionally approved Rx new animal drug, any secondary container labeling would be required to comply with proposed § 201.405(d).

If a package insert is not provided with an approved or conditionally approved Rx new animal drug, then secondary container labeling would be required, and the secondary container labeling would be required to provide full prescribing information (see proposed § 201.405(a)). If full prescribing information is provided on the secondary container labeling, in accordance with section 201(k) of the FD&C Act, proposed § 201.405(a) would allow the secondary container labeling to exclude any portions of full prescribing information that would be required to appear on the label if such information is easily legible through the secondary container (see proposed in § 201.405(d)).

The proposed rule would require the following information to be presented in full prescribing information for approved or conditionally approved Rx animal drugs and in the following order:

a. Drug product identification. The proposed rule would require this section of full prescribing information to include the proprietary name of the finished drug product and the established name of the drug product. If not included as part of the established name of the drug product, the route(s) of administration and dosage form of the finished drug product would be required to be included in this section as well (see proposed § 201.405(a)(1)(i) through (iv)).

The established name and strength or concentration of each active ingredient would also be required. The strength or concentration of each active ingredient would be allowed to be excluded from full prescribing information provided on a package insert if the package insert applies to multiple strengths or concentrations for the same Rx new animal drug (see proposed § 201.405(a)(1)(v)).

If FDA determines that identifying the pharmacological class of an Rx new animal drug on labeling would be helpful in facilitating its safe and effective use by the prescribing veterinarian, the proposed rule would require that the pharmacological class be included in this section of full prescribing information (see proposed § 201.405(a)(1)(vi)).

For Rx new animal drugs that are controlled substances, symbols provided in part 1302 (21 CFR part

1302) to identify the controlled substance schedule would also appear in this section of full prescribing information. See proposed § 201.405(a)(1)(vii).

Prescription statement. The proposed rule would require this section of full prescribing information to include the prescription statement, ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.'' Prescription new animal drugs are limited to use under the professional supervision of a licensed veterinarian (section 503(f)(1)(A) of the FD&C Act). The prescription statement would indicate that the Rx new animal drug is restricted to use by or under the order of a licensed veterinarian. Including the prescription statement on full prescribing information would be consistent with its inclusion on the label for Rx new animal drugs, which is required by section 503(f)(4) of the FD&C Act. The requirement for including the prescription statement as part of full prescribing information is proposed under the authority granted to FDA under sections 502(a), 201(n), and 701(a) of the FD&C Act. See proposed § 201.405(a)(2).

c. Conditional approval statement. For conditionally approved Rx new animal drugs, the proposed rule would require this section of full prescribing information to include, in accordance with section 571(f)(1)(A) of the FD&C Act, the statement indicating conditional approval by FDA and the application number: ''conditionally approved by FDA pending a full demonstration of effectiveness under application number [insert number]''. This statement would be required to be prominent and conspicuous (see proposed § 201.405(a)(3)).

d. Boxed warnings. For Rx new animal drugs requiring boxed warnings, the proposed rule would require this section of full prescribing information to include the boxed warnings. Boxed warnings convey the most significant risks associated with the use of a Rx new animal drug. If applicable to the product, they would appear at this prominent location. An upper case ''WARNING'' heading would be included in the box, and the box, heading, and contents would be bolded. The boxed warning would be brief, with reference to more detailed information in other sections of full prescribing information if applicable (see proposed § 201.405(a)(4)).

e. Extralabel use prohibition statement. For approved new animal drugs prohibited from extralabel use, in accordance with § 530.41 (21 CFR 530.41), the proposed rule would require this section of full prescribing information to include an extralabel use prohibition statement that begins with the phrase: ''Federal law prohibits the extralabel use of this drug . . .'' and concludes with a description of the prohibition as described in § 530.41 (see proposed § 201.405(a)(5)). For example, ''Federal law prohibits the extralabel use of this drug in lactating dairy cows.''

Certain new animal drugs are prohibited from extralabel use in some or all animals, in accordance with § 530.41. This information is critical for inclusion on labeling. If a user fails to comply with an extralabel use prohibition statement, there could be serious safety consequences for the target animal, or in the case of a food-producing animal, also for humans consuming food derived from the target animal.

f. ''*Description.*'' The proposed rule would require this section of full prescribing information to have the heading ''Description,'' followed by a description of the new animal drug. The description would include the proprietary name of the finished drug product and established name of the drug product, and the route(s) of administration and dosage form if not included as part of the established name. The description would also include identifying characteristics of the dosage form, such as color, shape, coating, scoring, and imprinting. All approved and available strengths or concentrations of the new animal drug to which full prescribing information applies would need to be identified in this section of full prescribing information. If the drug product was sterile, this fact would also be identified in this section of full prescribing information (see proposed § 201.405(a)(6)).

The established name of each inactive ingredient would be required to be included in the ''Description'' section of full prescribing information. The proposed rule would require all inactive ingredients to be listed in decreasing order of predominance, by weight or concentration (see proposed § 201.405(a)(6)(viii)). FDA believes that listing inactive ingredients in decreasing order of predominance based on either weight or concentration would provide the most clinically useful information to users.

In accordance with section 502(e)(1)(A)(iii) of the FD&C Act, the proposed rule would not require the listing of inactive ingredients on full prescribing information under circumstances that would result in disclosure of trade secret information. Therefore, where sponsors believe the listing of inactive ingredients on product labeling would result in disclosure of trade secret information, they would be able to request exemption from this labeling requirement under proposed § 201.411. If an exemption from the listing of inactive ingredients to avoid divulgence of trade secret information is granted under § 201.411, this section of full prescribing information would be required to state: ''Certain inactive ingredients are not listed to avoid disclosing trade secret information.'' (see proposed § 201.405(a)(6)(viii)(A)).

Section 502(e)(1)(B) of the FD&C Act allows an exemption from listing inactive ingredients on the label of Rx drugs if doing so would be impracticable. The current regulations at § 201.105(b)(5) for Rx animal drugs state that names of flavorings, perfumes, certain color additives, and ''trace amounts of harmless substances added solely for individual product identification'' may be exempt from listing on the labels for products other than for oral use. The regulations at § 201.105 predate the requirements in section 502(e)(1)(B) of the FD&C Act and are outdated. The proposed rule would replace the requirements for labels for approved or conditionally approved Rx new animal drugs currently provided in § 201.105(b) with the requirements in proposed § 201.405(b) and (c) (see discussion in section V.D.2. and 3). Thus, the labels for approved or conditionally approved Rx new animal drugs would no longer qualify for the exemptions currently identified in § 201.105(b)(5).

If under proposed § 201.411 FDA grants an exemption from listing inactive ingredients because their listing would be impracticable, this section of full prescribing information would need to state the following: ''Certain inactive ingredients are not listed because their listing would be impracticable.'' (see proposed § 201.405(a)(6)(viii)(B)).

g. ''*Indications for Use.*'' This section of full prescribing information would be required to have the heading ''Indications for Use,'' followed by the approved or conditionally approved indication(s) and target animal(s) in the following format: ''For [indication(s)] in [target animal(s)]'' (see proposed § 201.405(a)(7)(i)).

Consistent with regulations for the labeling of Rx human products in § 201.57(c)(2)(i)(A), if a Rx new animal drug is approved or conditionally approved for use only under specific conditions, *e.g.,* in conjunction with a primary mode of therapy, special diet, surgery, behavioral modification, or some other drug, the proposed rule

would require that this information be specified in the ''Indications for Use'' section of full prescribing information (see proposed § 201.405(a)(7)(ii)).

If, in approving or conditionally approving an application, FDA requires, for safety and/or effectiveness reasons, a statement(s) on labeling identifying animals for which the Rx new animal drug has not been approved or conditionally approved, the proposed rule would require that statement(s) to appear in the ''Indications for Use'' section of full prescribing information (see proposed § 201.405(a)(7)(iii)). We currently require the statement(s) proposed in § 201.405(a)(7)(iii) to appear on labeling of some approved new animal drugs, particularly new animal drugs for use in food-producing animals, to clarify the target animal for which the drug is approved. The statements are typically required if we determine that unapproved use of a drug in animals similar to the target animal(s) is reasonably foreseeable and we believe that inclusion of such a statement on the labeling of the new animal drug could increase the safe and effective use of the drug. For example, feedlot beef cattle are not intended to provide milk for human consumption. Therefore, we will not likely require an evaluation of the human food safety of a new animal drug in lactating dairy cows if the new animal drug is only to be approved for use in feedlot cattle. However, we will often require a statement on labeling that the drug is not for use in lactating dairy cows intended to produce milk for human consumption to avoid use of the drug in this unapproved and unevaluated manner.

The statement(s) proposed in § 201.405(a)(7)(iii) is not intended to prohibit extralabel use of approved new animal drugs allowed under specific circumstances, in accordance with section 512(a)(4) of the FD&C Act and part 530 (21 CFR part 530), but would help to clarify that some specific uses are extralabel and have not been evaluated for safety and effectiveness by FDA. Currently, there is no uniform place on the labeling for new animal drugs for such statements to appear. If we require such statements on labeling to ensure safe and effective use of a new animal drug, the proposed rule would require the statements to be placed within the ''Indications for Use'' section of full prescribing information. Inclusion of such statements in the ''Indications for Use'' section would not necessarily preclude also including similar statements in other sections or subsections of full prescribing information if warranted. For example, it may be appropriate to include a similar statement as a residue warning statement in the ''Withdrawal Periods and Residue Warnings'' subsection to expand upon human food safety risks of the extralabel use of the new animal drug in animals other than the target animal.

h. ''*Dosage and Administration.*'' The proposed rule would require this section of full prescribing information to have the heading ''Dosage and Administration,'' followed by the dosage and administration information for the new animal drug for each indication and target animal (see proposed § 201.405(a)(8)).

Sometimes FDA requires additional labeling for Rx new animal drugs that provides important information for the animal owner or person treating the animal. If such additional labeling is required, the proposed ''Dosage and Administration'' section of full prescribing information would advise the veterinarian to provide the additional labeling to the animal owner or person treating the animal (see proposed § 201.405(a)(8)(i)).

The remainder of this section of full prescribing information would be required to include information necessary for treatment of the animal with the Rx new animal drug in accordance with FDA approval or conditional approval, including: route(s) of administration and specific site(s) of administration, if applicable; dose or dose range; intervals between doses, if applicable; and duration of treatment. For some injectable products, FDA may require a statement of the maximum volume per injection site to facilitate the drug's safe and effective use, and the proposed rule would require this information to be included in this section of full prescribing information. Also, certain animal populations may require modifications to the dosage and administration for safe and effective use. These modifications would be required to appear in this section of full prescribing information. Other required dosage and administration information would also be included in this section of full prescribing information. See proposed § 201.405(a)(8).

i. ''*Contraindications.*'' For Rx new animal drugs with contraindications, the proposed rule would require this section of full prescribing information to have the heading ''Contraindications,'' followed by the contraindications (see proposed § 201.405(a)(9)). As defined in proposed § 201.403, a contraindication would include any situation in which the new animal drug should not be used because the risk of use clearly outweighs any possible benefit to the animal and includes only known hazards.

j. ''*Warnings and Precautions.*'' The proposed rule would require this section of full prescribing information for all approved or conditionally approved Rx new animal drugs, and it would have the heading ''Warnings and Precautions'' (see proposed § 201.405(a)(10)). As defined in proposed § 201.403, warnings would describe any serious adverse reactions or potential hazards associated with the use of the new animal drug. In addition, precautions would be defined as any special care to be exercised for safe and effective use of the new animal drug, which may include recommended screening, monitoring, or diagnostic tests. Multiple subsections, if applicable, would be included in the ''Warnings and Precautions'' section of full prescribing information as described below and in the following order, and the warnings and precautions would be provided in the applicable subsection:

i. ''*Withdrawal Periods and Residue Warnings*'' *or* ''*Withdrawal Periods.*'' All Rx new animal drugs approved or conditionally approved for use in food-producing animals would be required to have as the first subsection of the ''Warnings and Precautions'' section of full prescribing information a subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods'' (see proposed § 201.405(a)(10)(i)). This subsection would provide all human food safety warnings, including milk discard times, withdrawal periods, and residue warning statements, as applicable to the new animal drug.

As defined in proposed § 201.403, a withdrawal period is the interval between the time of the last administration of a new animal drug and the time when the animal can be safely slaughtered for food. Withdrawal periods apply to all food-producing animals. As defined in proposed § 201.403, a milk discard time is the interval between the time of the last administration of a new animal drug and the time when the milk can be safely consumed. Milk discard times apply to female animals that produce milk for human consumption. A new animal drug approved for use in female animals that produce milk for human consumption may have both a milk discard time and a withdrawal period.

As defined in proposed § 201.403, a residue warning statement warns against the use of the new animal drug in animals for which the withdrawal period and/or milk discard time has not been determined, and/or provides other

information to prevent illegal drug residues in food products from animals treated with the new animal drug.

If there are any residue warning statements for the new animal drug, the proposed rule would require this subsection of full prescribing information to have the title ''Withdrawal Periods and Residue Warnings.'' If there are no residue warning statements associated with the new animal drug, this subsection of full prescribing information would be required to have the title ''Withdrawal Periods'' (see proposed § 201.405(a)(10)(i)(A)).

If the new animal drug is approved or conditionally approved for use in food-producing animals excluding female animals that produce milk for human consumption, the proposed rule would require this subsection of full prescribing information to include the withdrawal period(s) followed by any residue warning statements (see proposed § 201.405(a)(10)(i)(B)).

If the new animal drug is approved or conditionally approved for use in food-producing animals excluding female animals that produce milk for human consumption and there is no withdrawal period, the proposed rule would require this subsection of full prescribing information to state, ''No withdrawal period is required when used according to labeling.'' This statement would be followed by any residue warnings statements (see proposed § 201.405(a)(10)(i)(C)).

If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption, the proposed rule would require this subsection of full prescribing information to include the milk discard time(s), followed by the withdrawal period(s), followed by any residue warning statements (see proposed § 201.405(a)(10)(i)(D)).

If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption, and there is a milk discard time(s) but no withdrawal period, the proposed rule would require this subsection of full prescribing information to include the milk discard time(s), followed by the statement, ''No withdrawal period is required when used according to labeling.'' This statement would be followed by any residue statements (see proposed § 201.405(a)(10)(i)(E)).

If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption and there is no milk discard time but there is a withdrawal period(s), the proposed rule would require this subsection of full prescribing information to include the withdrawal period(s), followed by the statement, ''No milk discard time is required when used according to labeling.'' This statement would be followed by any residue warnings statements (see proposed § 201.405(a)(10)(i)(F)).

If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption and there is no milk discard time and no withdrawal period, the proposed rule would require this subsection of full prescribing information to state, ''No milk discard time and no withdrawal period is required when used according to labeling.'' This statement would be followed by any residue warnings statements (see proposed § 201.405(a)(10)(i)(G)).

Currently, new animal drugs approved for use in food-producing animals that have no milk discard time and/or withdrawal period may or may not indicate this information on labeling. If this information is not provided on labeling, potentially it could be confusing to the user of the new animal drug as to whether or not there is a milk discard time or withdrawal period for the new animal drug. Requiring this subsection of full prescribing information for all new animal drugs approved or conditionally approved for use in food-producing animals, and requiring a statement, if appropriate, to indicate that there is no milk discard time or withdrawal period when the new animal drug is used according to labeling, will better ensure the safe use of animal drugs in food-producing animals.

To further highlight for users this critical subsection of full prescribing information, the title of this subsection and all information in this subsection would be required to be centered and placed entirely within compressed arrows, in accordance with proposed § 201.404(g)(8). The compressed arrows would be black for package inserts, or a color that clearly contrasts from background colors for other approved labeling (see proposed § 201.405(a)(10)(i)(A)). Currently, the compressed arrows are used voluntarily, although not consistently, on the labeling for many new animal drugs approved for use in food-producing animals. Currently other statements not associated with human food safety may also appear within the compressed arrows. The proposed rule would limit the use of compressed arrows to the subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods'' (see proposed § 201.404(g)(6)), which would only contain human food safety information.

ii ''*User Safety Warnings.*'' The proposed rule would require this subsection of the ''Warnings and Precautions'' section of full prescribing information to have the heading ''User Safety Warnings,'' followed by the user safety warnings. As defined in proposed § 201.403, a user safety warning would be a warning that identifies serious adverse reactions or potential hazards to human health associated with human exposure during use of a new animal drug via contact, inhalation, ingestion, injection, or by other means. This information would be required to prevent or decrease the risk of harm to humans.

The first statements that would be included in this subsection of full prescribing information are: ''Not for use in humans. Keep out of reach of children.'' The subsection would next list all additional user safety warnings listed in decreasing order of severity or frequency. The final information that would be included in this subsection of full prescribing information would be a sentence explaining how to obtain Safety Data Sheet(s) for the drug. Chemical manufacturers, distributors, and/or importers are required pursuant to 29 CFR 1910.1200(g) to provide Safety Data Sheets for each hazardous chemical to downstream users to communicate information on these hazards. Safety Data Sheets include information such as the properties of each chemical; their physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. The sentence in this subsection of full prescribing information would be required to be formatted as follows: ''To obtain a Safety Data Sheet(s), contact [insert name of manufacturer] at [insert manufacturer's telephone number] or [insert manufacturer's website].'' See proposed § 201.405(a)(10)(ii).

iii. ''*Animal Safety Warnings and Precautions.*'' For Rx new animal drugs with target animal safety warnings and precautions, the proposed rule would require this subsection of the ''Warnings and Precautions'' section of full prescribing information to have the heading ''Animal Safety Warnings and Precautions,'' followed by the target animal safety warnings and precautions (see proposed § 201.405(a)(10)(iii)). Target animal safety warnings identify any serious adverse reactions or potential hazards to the target animal(s) associated with the use of the new animal drug. Precautions for Rx new

animal drugs often include recommendations for specific screening, monitoring, diagnostic tests, or special care that should be taken by the prescribing veterinarian for safe and effective use of the new animal drug (see definition in proposed § 201.403). The heading of the subsection would include the term ''animal safety warnings'', *i.e.,* ''Animal Safety Warnings and Precautions,'' because we believe the term ''animal safety warnings'' is more familiar to users of Rx new animal drugs than ''target animal safety warnings.''

Precautions are sometimes difficult to distinguish from target animal safety warnings. Currently, target animal safety warnings and precautions are sometimes presented separately on the labeling for Rx new animal drugs. However, because the two sets of information are often closely related, it is advantageous to combine them into one subsection of full prescribing information.

Warnings and precautions are combined in the ''Highlights'' and ''Full Prescribing Information'' for human Rx drugs and biologics (see §§ 201.56 and 57). Similarly, combining target animal safety warnings and precautions in the ''Animal Safety Warnings and Precautions'' subsection of full prescribing information would be less burdensome for sponsors of Rx new animal drugs because sponsors would not be required to distinguish one from the other.

iv. ''*Environmental Warnings.*'' For approved or conditionally approved new animal drugs that have environmental warnings, the proposed rule would require this subsection of the ''Warnings and Precautions'' section of full prescribing information to have the heading ''Environmental Warnings,'' followed by the environmental warnings (see proposed § 201.405(a)(10)(iv)). FDA's regulations at 21 CFR part 25 implementing the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* address the environmental impact considerations required for products regulated by FDA, including new animal drugs. Under NEPA, the responsible Agency official examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action (see 21 CFR 25.40(e)). In some instances, sponsors may choose to include environmental warnings on the labeling for their new animal drugs as a means to mitigate or reduce the potential for environmental impacts to occur from the use or disposal of the drug (see 21 CFR 25.45). These warnings would generally include information to prevent or decrease the risk of any environmental effects. The proposed rule would require any environmental warnings applicable to the new animal drug that are included in an approved or conditionally approved application be provided in this subsection of full prescribing information (see proposed § 201.405(a)(10)(iv)).

v. ''*Other Warnings.*'' For new animal drugs having warnings not more appropriately placed in other ''Warnings and Precautions'' subsections, the proposed rule would require the last subsection of the ''Warnings and Precautions'' section of full prescribing information to have the heading ''Other Warnings,'' followed by those warnings (see proposed § 201.405(a)(10)(v)).

k. ''*Adverse Reactions.*'' For Rx new animal drugs that we determine have adverse reactions, this section of full prescribing information would be required to have the heading ''Adverse Reactions,'' followed by the adverse reactions (see proposed § 201.405(a)(11)). Adverse reactions would be defined in proposed § 201.403 as undesirable effects, reasonably associated with the use of the drug product, that may occur as part of the pharmacological action of the drug or that may be unpredictable in occurrence. The proposed rule would require this section of full prescribing information to include adverse reactions that occur with use of the Rx new animal drug and with use of drugs in the same pharmacologically active and chemically related classes, if applicable. Furthermore, we may require additional information as necessary for the prescribing veterinarian to interpret the adverse reactions, such as the total number of animals exposed to the drug and the extent and nature of exposure.

The proposed rule would also require that adverse reactions be presented within the following categories, as applicable, in decreasing order of severity or frequency: preapproval experience, foreign market experience known prior to U.S. approval for drugs also commercially marketed outside of the United States, and post-approval experience (see proposed § 201.405(a)(11)). For previously approved Rx new animal drugs for which the labeling would be updated in accordance with the schedule provided in this rule, if the preapproval experience and/or foreign market experience categories were not included on full prescribing information when the drug was approved, we may allow one or both of these subsections to be excluded from the ''Adverse Reactions'' section of full prescribing information if we determine that including such information is not necessary to ensure the safe and effective use of the drug. Post-approval experience would typically be added to labeling of the drug after it has been approved in the United States and if additional adverse drug experiences (as defined by § 514.3) associated with the use of the drug have been identified.

l. ''*Contact Information.*'' The proposed rule would require this section of full prescribing information to have the heading ''Contact Information,'' followed by the sponsor's contact information for veterinarians or consumers to facilitate requesting additional information or to report suspected adverse drug experiences. FDA's contact information for voluntary reporting of adverse drug experiences for animal drugs would also be required. Requiring contact information on new animal drug labeling increases the likelihood that a user will report adverse drug events to the sponsor and/or to the Center for Veterinary Medicine (CVM). Increasing the likelihood of receiving adverse drug event reports would allow new animal drug sponsors and CVM to better monitor and detect emerging safety issues with approved or conditionally approved new animal drugs on the market. Any increase in adverse drug event reporting and monitoring resulting from this proposed requirement would benefit both animal and human health.

The sponsor's contact information would be the name of the manufacturer, packer, or distributor, whichever is identified in the ''Name and place of business'' section of full prescribing information per proposed § 201.405(a)(22). If more than one business is identified in the ''Name and place of business'' section of full prescribing information, the drug sponsor would select the most appropriate of these businesses to use in the ''Contact Information'' section to provide additional information about the Rx new animal drug and to contact regarding suspected adverse drug experiences.

The statements in this section of full prescribing information would be required to be structured as follows: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report suspected adverse drug experiences, contact [insert name of business] at [insert business telephone number]. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at [insert current

FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' See proposed § 201.405(a)(12). Sponsors can search FDA's website or contact FDA by telephone to find the current FDA telephone number and web address for voluntary reporting of adverse drug experiences for animal drugs.

m. ''*Information for Animal Owner.*'' For Rx new animal drugs required to have additional information to be communicated by the prescribing veterinarian to the animal owner or person treating the animal to ensure safe and effective use of the Rx new animal drug, the proposed rule would require this section of full prescribing information to have the heading ''Information for Animal Owner,'' followed by the specific information.

For some new animal drugs, FDA may determine it is necessary for sponsors to provide the animal owner or person treating the animal with additional labeling, such as a ''client information sheet,'' to ensure the safe and effective use of the Rx new animal drug. If we determine that such additional labeling is necessary, a printed copy of the additional labeling would be required to be attached to or accompany the package insert or secondary container labeling if no package insert is provided. See proposed § 201.405(a)(13).

n. ''*Clinical Pharmacology.*'' For Rx new animal drugs required to include clinical pharmacology information on labeling, the proposed rule would require this section of full prescribing information to have the heading ''Clinical Pharmacology,'' followed by the clinical pharmacology information for the Rx new animal drug in the target animal(s). The required information would be relevant for understanding the relationship between dose, systemic drug exposure, safety, and clinical effectiveness. This information may help the prescribing veterinarian to predict how the Rx new animal drug would perform in the different animal patient populations likely to be encountered under clinical use conditions. This section of full prescribing information would be required to include the following three separate subsections, as applicable to the Rx new animal drug: ''Mechanism of action,'' ''Pharmacodynamics,'' and ''Pharmacokinetics'' (see proposed § 201.405(a)(14)).

o. ''*Microbiology.*'' For antimicrobial Rx new animal drugs, the proposed rule would require this section of full prescribing information to have the heading ''Microbiology,'' followed by a description of microbiologic data associated with the studies used to support the effectiveness of the drug against the indicated pathogens. The microbiology data would be required to be restricted to organisms named in the approved or conditionally approved indications.

If in vitro data for antimicrobial new animal drugs are included in this section of full prescribing information and the data have not been correlated to clinical effectiveness, then such in vitro data would be required to be immediately preceded by the following statement: ''The following in vitro data are available, but their clinical significance is unknown.'' See proposed § 201.405(a)(15).

p. ''*Target Animal Safety.*'' The proposed rule would require this section of full prescribing information to have the heading ''Target Animal Safety,'' followed by a summary of the basis for the conclusion that the new animal drug is safe in the target animal(s) when used as approved or conditionally approved (see proposed § 201.405(a)(16)).

q. ''*Effectiveness.*'' The proposed rule would require this section of full prescribing information to have the heading ''Effectiveness,'' followed by a summary of the basis for the conclusion that the new animal drug is effective in the target animal(s) when used as approved. For conditionally approved drugs, the ''Effectiveness'' section of full prescribing information would be required to include a summary of the basis for the reasonable expectation of effectiveness (see proposed § 201.405(a)(17)).

r. ''*Net Contents.*'' The proposed rule would require this section of full prescribing information, when presented on the secondary container labeling, to have the heading ''Net Contents,'' followed by the contents of the secondary container. The proposed rule would exclude a ''Net Contents'' section from package inserts (see proposed § 201.405(a)(18)).

s. ''*How Supplied.*'' The proposed rule would require this section of full prescribing information to have the heading ''How Supplied,'' followed by information on available drug strengths, concentrations, and container sizes to which the labeling applies. The information in this section would be required to be revised if new strengths, concentrations, or container sizes are added (see proposed § 201.405(a)(19)).

t. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of full prescribing information to have the heading ''Storage, Handling, and Disposal'' (see proposed § 201.405(a)(20)). Drug storage information would be included in this section and may include, for example, required temperature, humidity, and/or light exposure conditions to maintain the potency of the Rx new animal drug until its established expiration date. Also, any handling and drug disposal information that we determine to be necessary for safe and effective use of the Rx new animal drug would be included in this section. Handling information may include, for example, recommendations to reseal reusable bottles promptly after opening and conditions necessary to maintain potency of reconstituted new animal drugs. Drug disposal information may include, for example, instructions on disposal of unused portions of new animal drugs remaining after treatment, as well as used needles and/or syringes.

u. NADA/ANADA approval statement. In accordance with section 502(w)(3) of the FD&C Act, by no later than September 30, 2023, approved new animal drugs must include the following statement on labeling: ''Approved by FDA under NADA # xxx–xxx''. By no later than September 30, 2023, approved generic Rx new animal drugs must include the following statement on labeling: ''Approved by FDA under ANADA # xxx–xxx''. For approved Rx new animal drugs, the proposed rule would require this section of full prescribing information to include the ''NADA approval statement,'' indicating the product's NADA number and that it was approved by FDA. For approved generic Rx new animal drugs that would be covered by these regulations (*i.e.,* those that reference an NADA that has been withdrawn for reasons other than safety or effectiveness or under section 512(e) of the FD&C Act and the ANADA's approval was not affected by the withdrawal), the proposed rule would require this section of full prescribing information to include the ''ANADA approval statement.'' The proposed rule would establish format requirements for the approval statement and would require that the approval statement not be so prominent as to obscure other required information. The approval statement could not be incorporated into a seal, stamp, logo, or graphic. See proposed § 201.405(a)(21).

v. Name and place of business. The proposed rule would require this section of full prescribing information to identify the name and place of business of the manufacturer, packer, or distributor (see proposed § 201.405(a)(22)).

w. ''*Lot Number and Expiration Date.*'' The proposed rule would require

this section of full prescribing information when provided on the secondary container labeling. Package inserts are excluded from this requirement because they might apply to multiple lots of secondary or immediate containers of the Rx new animal drug. When full prescribing information is provided on the secondary container labeling, this section would be required to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the Rx new animal drug within the secondary container (see proposed § 201.405(a)(23)). Should a problem be reported to FDA, a lot or control number would help us more easily to identify and trace back a specific lot of a product. The proposed rule would also require this section to include the expiration date of the Rx new animal drug within the secondary container, in accordance with § 201.17 (21 CFR 201.17). An expiration date better ensures that the new animal drug would not be used after it expires.

Alternatively, the proposed rule would allow for this section of full prescribing information to refer to the location on the secondary container labeling or secondary container where the lot or control number and expiration date are printed (see proposed § 201.405(a)(23)). As an example, if the lot number and expiration date are printed on the bottom flap of a secondary container, then the secondary container labeling may state in this section, ''See carton bottom flap for lot number and expiration date.'' However, in accordance with § 201.17, the proposed rule would allow an expiration date to be excluded from the secondary container labeling or secondary container if the expiration date provided on the label or immediate container is easily legible through the secondary container.

x. ''*Revision Date.*'' The proposed rule would require this section of full prescribing information to have the heading ''Revision Date,'' followed by the date of the most recent revision of the component of labeling that provides full prescribing information, listing the month followed by the year (see proposed § 201.405(a)(24)). This information is important to ensure that the most current approved version of the labeling is being used.

2. Prescription New Animal Drug Label (Rx Label) (Proposed § 201.405(b))

The proposed rule would establish content and format requirements for the information presented on the label for approved or conditionally approved Rx new animal drugs (Rx label) (see proposed § 201.405(b)). As defined in proposed § 201.403, ''label'' has the same meaning as given in section 201(k) of the FD&C Act, which defines the term ''label'' to mean a display of written, printed, or graphic matter upon the immediate container of any article. As defined in proposed § 201.403, the immediate container means the container in contact with the new animal drug, and it excludes package liners.

Proposed § 201.405(b) would apply to Rx labels that are of adequate size to contain the proposed required information per that paragraph, whereas proposed § 201.405(c) would apply to small labels for Rx new animal drugs that are not of adequate size to contain all the proposed required information in proposed § 201.405(b).

Prescription new animal drugs labels to which § 201.405(b) would apply may consist of a single panel, a front panel and one side or back panel, or a front panel and multiple side and/or back panels, and the proposed rule would provide for such label designs (see § 201.405(b)). For Rx labels with a front panel and one side or back panel, the proposed rule would require certain information for the front panel (see proposed § 201.405(b)(1)), and the side or back panel (see proposed § 201.405(b)(2)). For Rx labels consisting of a single panel, the proposed rule would require the information identified in proposed § 201.405(b)(1) followed by the information identified in proposed § 201.405(b)(2), in order, on the single panel. For Rx labels with a front panel and multiple side and/or back panels, the information identified in proposed § 201.405(b)(1) followed by the information identified in proposed § 201.405(b)(2) would be required in order, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information in proposed § 201.405(b)(1) and (b)(2) was presented. In all instances, the information proposed in § 201.405(b)(2)(iii) and (iv), *i.e.,* ''Active Ingredient'' or ''Active Ingredients'' and ''Inactive Ingredients,'' would need to appear on the same panel.

a. Front panel. The proposed rule would require the following information to be presented on the front panel of the Rx label for an approved or conditionally approved Rx new animal drug and in the following order. Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information.

i. *Drug product identification.* The proposed rule would require this section of the Rx label to include drug product identification information (see proposed § 201.405(b)(1)(i)). This information may help the user quickly and correctly identify the product and distinguish it from other, similar products. The information included in this section of the Rx label would include the same information as that in the drug product identification section of full prescribing information, as described in proposed § 201.405(a)(1), in addition to a statement that the drug product is sterile, if applicable. Full prescribing information would require a drug product identification section and a ''Description'' section. Full prescribing information for sterile Rx new animal drugs would be required to identify in the ''Description'' section that the drug is sterile. However, due to space limitations, no ''Description'' section is proposed for the Rx label. Instead, the drug product identification section of the Rx label for sterile Rx new animal drugs would be required to state that the drug product is sterile. See proposed § 201.405(b)(1)(i).

ii. *Prescription statement.* The proposed rule would require this section of the Rx label to include the prescription statement (see proposed § 201.405(b)(1)(ii)). In accordance with section 503(f)(4) of the FD&C Act, all Rx new animal drugs must state on the label: ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

iii. *Conditional approval statement.* For conditionally approved new animal drugs, the proposed rule would require this section of the Rx label to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information (see proposed § 201.405(b)(1)(iii)).

iv. *Boxed warnings.* For approved or conditionally approved Rx new animal drugs requiring boxed warnings, the proposed rule would require this section of the Rx label to include the boxed warnings, as described in proposed § 201.405(a)(4) for full prescribing information (see proposed § 201.405(b)(1)(iv)).

v. ''*Indications for Use.*'' The proposed rule would require this section of the Rx label to have the heading ''Indications for Use,'' followed by the ''Indications for Use'' section, as described in proposed § 201.405(a)(7) for full prescribing information. If we determine that there is insufficient space on the Rx label for the complete ''Indications for Use'' section as described in proposed § 201.405(a)(7), then the proposed rule would require

the sponsor to include in this section of the Rx label the statement required in proposed § 201.405(a)(7)(i), *i.e.,* ''For [indication(s)] in [target animal(s)]''. If there is insufficient space on the Rx label for the statement in proposed § 201.405(a)(7)(i), then an abbreviated version of the statement would be required: ''For [abbreviated indication(s)] in [target animal(s)]''. In either situation where there is insufficient space on the Rx label for the complete ''Indications for Use'' section as specified in proposed § 201.405(a)(7), the required statement would be followed by one of the following statements: ''See package insert for complete 'Indications for Use' '' if full prescribing information is provided on a package insert; or ''See package labeling for complete 'Indications for Use' '' if full prescribing information is provided on the secondary container labeling. See proposed § 201.405(b)(1)(v).

The complete ''Indications for Use'' section as described in proposed § 201.405(a)(7) may exceed the available space on the Rx label if, for example, it includes specific conditions of use (proposed § 201.405(a)(7)(ii)) or animals for which the new animal drug is not approved or conditionally approved (proposed § 201.405(a)(7)(iii)), and/or the indication(s) is lengthy and/or complex. For example, a new animal drug approved to treat and control multiple species of roundworms, lungworms, lice, and mites in beef cattle would ordinarily identify all of those species in the ''Indications for Use'' section of the label. However, if space is insufficient on the Rx label to provide the identity of all of the species of the roundworms, lungworms, lice, and mites for which the drug is effective, an acceptable ''abbreviated'' version of the ''Indications for Use'' section on the Rx label for this product might include, for example, ''For treatment and control of certain species of roundworms, lungworms, lice, and mites in beef cattle. See package insert for complete 'Indications for Use'.''

vi. *Extralabel use prohibition statement.* For approved Rx new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of the Rx label to include the extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information (see proposed § 201.405(b)(1)(vi)).

vii. ''*Withdrawal Periods and Residue Warnings*'' or ''*Withdrawal Periods.*'' For new animal drugs approved or conditionally approved for use in food-producing animals, the proposed rule would require this section of the Rx label to have the heading ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods,'' followed by all human food safety warnings, including milk discard times, withdrawal periods, and residue warning statements, as described in proposed § 201.405(a)(10)(i) for full prescribing information. If there is insufficient space on the front panel of Rx labels with only a front panel and one side or back panel, the proposed rule would require this section to be provided on the side or back panel of the Rx label immediately following the full prescribing information statement specified in proposed § 201.405(b)(2)(i). See proposed § 201.405(b)(1)(vii).

viii. ''*Net Contents.*'' The proposed rule would require this section of the Rx label to have the heading ''Net Contents,'' followed by the contents of the immediate container, in accordance with § 201.51 (see proposed § 201.405(b)(1)(viii)).

ix. *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the Rx label to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information (see proposed § 201.405(b)(1)(ix)).

b. Side or back panel. The proposed rule would require the following information to be presented on the side or back panel of the Rx label for an approved or conditionally approved Rx new animal drug in the following order (see proposed § 201.405(b)(2)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information.

i. *Full prescribing information statement.* The proposed rule would require this section of the Rx label to include one of two statements (see proposed § 201.405(b)(2)(i)). If full prescribing information is provided on the package insert, the following statement would be used: ''Before using this drug, read package insert for full prescribing information.'' If full prescribing information is provided on the secondary container labeling, the following statement would be used: ''Before using this drug, read package labeling for full prescribing information.'' Because full prescribing information would not be provided on the Rx label, the purpose of the statements would be to remind the veterinarian to read full prescribing information before using the Rx new animal drug.

ii. ''*Dosage and Administration.*'' The proposed rule would require this section of the Rx label to have the heading ''Dosage and Administration,'' followed by the ''Dosage and Administration'' section, as described in proposed § 201.405(a)(8) for full prescribing information. If there is insufficient space on the Rx label for the complete requirements as specified in proposed § 201.405(a)(8), or if it is necessary for additional information provided in full prescribing information that is not provided on the Rx label to be read before administering the drug (*e.g.,* complete warnings and precautions, contraindications, and/or target animal safety), then FDA may exclude this section from the Rx label (see proposed § 201.405(b)(2)(ii)). For example, with respect to the latter situation, if careful observation of the animal after dosing is advised to watch for adverse reactions, this information typically would be described in the ''Animal Safety Warnings and Precautions'' subsection, which would not be required on the Rx label but would be required on full prescribing information. Excluding the ''Dosage and Administration'' section from the Rx label in this situation helps to ensure that the veterinarian would read full prescribing information, which would include the ''Dosage and Administration'' section as well as the ''Animal Safety Warnings and Precautions'' subsection, before treating the animal. Users would also be reminded to read full prescribing information before using the drug via the full prescribing information statement that would be required in the previous section of the Rx label by proposed § 201.405(b)(2)(i).

iii. ''*Active Ingredient*'' or ''*Active Ingredients.*'' The proposed rule would require this section of the Rx label to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and strength or concentration of each active ingredient. If the Rx new animal drug contains one active ingredient, the proposed rule would require this section of the Rx label to be entitled ''Active Ingredient.'' If the Rx new animal drug contains more than one active ingredient, the proposed rule would require this section of the Rx label to be entitled ''Active Ingredients.'' The requirement to provide established name and strength or concentration of each active ingredient on the Rx label would be consistent with the requirement for the established name and quantity or proportion of each active ingredient on the label of prescription drugs, in

accordance with section 502(e)(1)(A)(ii), (B), and (g) of the FD&C Act (see proposed § 201.405(b)(2)(iii)). This information is currently required to be on the label for Rx animal drugs, in accordance with § 201.105(b)(4). Proposed § 201.405(b) and (c) would establish the content and format requirements for the label for approved or conditionally approved Rx new animal drugs and would replace the requirements for the label of approved or conditionally approved Rx new animal drugs currently provided in § 201.105(b). Furthermore, § 201.105 would be amended to refer to proposed § 201.405 for the content and format requirements for labeling components for approved or conditionally approved Rx new animal drugs.

iv. ''*Inactive Ingredients.*'' The proposed rule would require this section of the Rx label to have the heading ''Inactive Ingredients,'' followed by the established name of each inactive ingredient, as described in proposed § 201.405(a)(6)(viii) for full prescribing information (see proposed § 201.405(b)(2)(iv)).

v. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the Rx label to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage, handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information (see proposed § 201.405(b)(2)(v)).

vi. *Name and place of business.* The proposed rule would require this section of the Rx label to identify the name and place of business of the manufacturer, packer, or distributor, as required in section 502(b) of the FD&C Act (see proposed § 201.405(b)(2)(vi)).

vii. ''*Lot Number and Expiration Date*'' or ''*Lot Number.*'' The proposed rule would require this section of the Rx label to have the heading ''Lot Number and Expiration Date'' or ''Lot Number,'' followed by the identifying lot or control number of the Rx new animal drug within the immediate container (see proposed § 201.405(b)(2)(vii)). A lot or control number would allow us to more easily identify and trace back a specific lot of a product should a problem be reported to FDA. We would also require this section of the Rx label to include the expiration date of the Rx new animal drug within the immediate container, in accordance with § 201.17.

An expiration date on the Rx label better ensures that the new animal drug would not be used after it expires. Alternatively, the proposed rule would allow for this section to refer to the location on the Rx label or immediate container where the lot or control number and expiration date are printed (see proposed § 201.405(b)(2)(vii)). As an example, if the lot number and expiration date are printed at the top of the immediate container, then the Rx label may state in this section, ''See top of container for lot number and expiration date.'' If the immediate container provides a single dose of the Rx new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, the proposed rule would not require an expiration date on the Rx label or immediate container, in accordance with § 201.17. Under such provision, this section of the Rx label would be required to be entitled ''Lot Number.''

viii. ''*Revision Date.*'' The proposed rule would require the last section of the Rx label to have the heading ''Revision Date,'' followed by the date of the most recent revision of the Rx label, listing the month followed by the year (see proposed § 201.405(b)(2)(viii)).

3. Prescription New Animal Drug Small Label (Rx Small Label) (Proposed § 201.405(c))

The proposed rule would establish content and format requirements for the small label for Rx new animal drugs (Rx small label) (see proposed § 201.405(c)). Some immediate containers, such as blister packs, pre-filled syringes, and small vials, are so small that only a minimal amount of information can be included on their label. The proposed rule would establish requirements for Rx small labels for approved or conditionally approved Rx new animal drugs (see proposed § 201.405(c)). We recognize that the size of the label is dependent upon the size of the immediate container. If an immediate container lacks sufficient space to contain a label that accommodates all of the information required by proposed § 201.405(b), the requirements of proposed § 201.405(c) would instead apply. We would ordinarily make this determination during the review of the new animal drug and its labeling, taking into consideration the readability and legibility of the information.

The proposed rule would require the following information to be presented on the Rx small label for an approved or conditionally approved Rx new animal drug and in the following order (see proposed § 201.405(c)).

a. Proprietary name of the finished drug product. The proposed rule would require this section of the Rx small label to include the proprietary name of the finished drug product (see proposed § 201.405(c)(1)). This requirement already exists for small labels for drugs in general in § 201.10(i)(1), but is repeated in these proposed regulations to include all requirements for labeling of approved or conditionally approved new animal drugs in proposed subpart H.

b. Established name of the drug product. The proposed rule would require this section of the Rx small label to include the established name of the drug product (see proposed § 201.405(c)(2)). This requirement already exists for small labels for drugs in general in § 201.10(i)(1), but is repeated in these proposed regulations to include all requirements for labeling of approved or conditionally approved new animal drugs in proposed subpart H.

c. Active ingredient(s). The proposed rule would require this section of the Rx small label to include the established name and strength or concentration of each active ingredient, which is consistent with the requirement for the established name and quantity or proportion of each active ingredient on the label of prescription drugs, in accordance with section 502(e)(1)(A)(ii), (B), and (g) of the FD&C Act (see proposed § 201.405(c)(3)). This information is currently required to be on the label for Rx animal drugs, in accordance with § 201.105(b)(4).

Proposed § 201.405(b) and (c) would establish the content and format requirements for the label for approved or conditionally approved Rx new animal drugs and would replace the requirements for the label of approved or conditionally approved Rx new animal drugs currently provided in § 201.105(b). Furthermore, § 201.105 would be amended to cross-reference proposed § 201.405 for the content and format requirements for labeling components for approved or conditionally approved Rx new animal drugs (see discussion in section V.I.).

d. Controlled substance symbol. For Rx new animal drugs that are controlled substances, the proposed rule would require this section of the Rx small label to include the controlled substance schedule symbol in accordance with part 1302 designating the schedule for the drug substance (see proposed § 201.405(c)(4)).

e. Prescription statement. The proposed rule would require this section of the Rx small label to state: ''Rx Animal Use'' (see proposed § 201.405(c)(5)). In accordance with section 503(f)(4) of the FD&C Act, the label for all Rx new animal drugs must include the following statement: ''Caution: Federal law restricts this drug to use by or on the order of a licensed

veterinarian.'' However, since 1960 (25 FR 12592) § 201.105(b)(6) exempts ''containers too small or otherwise unable to accommodate a label with sufficient space'' to include the full prescription statement provided that the full statement may be placed on the outer container only. We are proposing the ''Rx Animal Use'' statement for a Rx small label for Rx new animal drugs. This statement would appropriately identify the Rx status of the new animal drug and would require minimal space.

f. ''*For [target animal(s)] only.*'' The proposed rule would require this section of the Rx small label to include a brief listing of the approved target animal(s) as follows: ''For [target animal(s)] only'' (see proposed § 201.405(c)(6)). The brief listing of the approved target animal(s) would be used in place of full ''Indications for Use'' information because Rx small labels lack sufficient space. This listing would not require as much space on the Rx small label.

g. Full prescribing information statement. The proposed rule would require this section of the Rx small label to include one of two statements. If full prescribing information is provided on the package insert, the following statement would be used: ''Read package insert for full prescribing information.'' If full prescribing information is provided on the secondary container labeling, the following statement would be used: ''Read package labeling for full prescribing information.'' See proposed § 201.405(c)(7). Because full prescribing information would not be provided on the Rx small label, the purpose of the statements would be to remind the veterinarian to read full prescribing information before using the Rx new animal drug.

h. ''*Net Contents.*'' The proposed rule would require this section of the Rx small label to have the heading ''Net Contents,'' followed by the contents of the immediate container, in accordance with § 201.51 (see proposed § 201.405(c)(8)).

i. Name and place of business. The proposed rule would require this section of the Rx small label to identify the name and place of business of the manufacturer, packer, or distributor, as required in section 502(b) of the FD&C Act (see proposed § 201.405(c)(9)).

j. ''*Lot, Exp. and Storage*'' or ''*Lot and Storage.*'' The proposed rule would require this section of the Rx small label to have the heading ''Lot, Exp. and Storage'' or ''Lot and Storage,'' followed by the identifying lot or control number of the Rx new animal drug within the immediate container (see proposed § 201.405(c)(10)). Should a problem be reported to FDA, a lot or control number would allow us more easily to identify and trace back a specific lot of a product. We would also require this section of the Rx small label to include the expiration date of the Rx new animal drug within the immediate container, in accordance with § 201.17. An expiration date on the Rx small label better ensures that the new animal drug would not be used after it expires.

The proposed rule would also require this section of the Rx small label to include drug storage information for the new animal drug (see proposed § 201.405(c)(10)). Storage information is necessary to maintain potency of the drug before its expiration date. Requiring this information on the Rx small label is needed for safe and effective use of new animal drugs. If the immediate container provides a single dose of the Rx new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, the proposed rule would not require an expiration date on the Rx small label or immediate container, in accordance with § 201.17. Under such provision, this section of the Rx small label would be required to be entitled ''Lot and Storage.''

k. ''*Revision Date.*'' The proposed rule would require this section of the Rx small label to have the heading ''Revision Date,'' followed by the date of the most recent revision of the Rx small label, listing the month followed by the year (see proposed § 201.405(c)(11)).

4. Labeling for Secondary Containers for Rx New Animal Drugs That Include a Package Insert (Rx Secondary Container Labeling) (Proposed § 201.405(d))

The proposed rule would establish content and format requirements for the information on the labeling for secondary containers of approved or conditionally approved Rx new animal drugs that include a package insert (Rx secondary container labeling) (see proposed § 201.405(d)). In this situation, the package insert would be required to include full prescribing information, as described in proposed § 201.405(a).

In accordance with section 201(k) of the FD&C Act, the Rx secondary container labeling could exclude any information described in proposed § 201.405(d) that would be required to appear on the Rx label or Rx small label (see proposed § 201.405(b) or (c), respectively) if such information on the Rx label or Rx small label was easily legible through the secondary container.

The Rx secondary container labeling to which proposed § 201.405(d) would apply may consist of a front panel and one side or back panel, or a front panel and multiple side and/or back panels. Proposed § 201.405(d) would provide for such Rx secondary container labeling designs. For Rx secondary container labeling with a front panel and one side or back panel, proposed § 201.405(d)(1) would provide required information for the front panel, and proposed § 201.405(d)(2) would provide required information for the side or back panel. For Rx secondary container labeling with a front panel and multiple side and/or back panels, the information identified in proposed § 201.405(d)(1) followed by the information identified in proposed § 201.405(d)(2) would be required in order, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information in proposed § 201.405(d)(1) and (d)(2) was presented. In all instances, the information proposed in § 201.405(d)(2)(v) and (vi), *i.e.,* ''Active Ingredient'' or ''Active Ingredients'' and ''Inactive Ingredients,'' would need to appear on the same panel.

a. Front panel. The proposed rule would require the following information to be presented on the front panel of the Rx secondary container labeling and in the following order (see proposed § 201.405(d)(1)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information.

i. *Drug product identification.* The proposed rule would require this section of the Rx secondary container labeling to include drug product identification (see proposed § 201.405(d)(1)(i)). The information would be the same as that included in the drug product identification section for full prescribing information, as described in proposed § 201.405(a)(1), and would also identify if the drug product is sterile. Full prescribing information would require a drug product identification section and a ''Description'' section. Full prescribing information for sterile Rx new animal drugs would be required to identify in the ''Description'' section that the drug is sterile. However, due to space limitations, no ''Description'' section would be required on the Rx secondary container labeling. Instead, the drug product identification section of the Rx secondary container labeling for sterile Rx new animal drugs would be required to state that the drug is sterile.

ii. *Prescription statement.* The proposed rule would require this section of the Rx secondary container

labeling to include the prescription statement, as described in proposed § 201.405(a)(2) for full prescribing information (see proposed § 201.405(d)(1)(ii)).

iii. *Conditional approval statement.* For conditionally approved Rx new animal drugs, the proposed rule would require this section of the Rx secondary container labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information (see proposed § 201.405(d)(1)(iii)).

iv. *Boxed warnings.* For approved or conditionally approved Rx new animal drugs requiring boxed warnings, the proposed rule would require this section of the Rx secondary container labeling to include the boxed warnings, as described in proposed § 201.405(a)(4) for full prescribing information (see proposed § 201.405(d)(1)(iv)).

v. ''*Indications for Use.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Indications for Use,'' followed by the ''Indications for Use'' section, as described in proposed § 201.405(a)(7) for full prescribing information (see proposed § 201.405(d)(1)(v)).

vi. *Extralabel prohibition statement.* For approved new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of the Rx secondary container labeling to include the extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information (see proposed § 201.405(d)(1)(vi)).

vii. ''*Net Contents.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Net Contents,'' followed by the contents of the secondary container (see proposed § 201.405(d)(1)(vii)).

viii. *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the Rx secondary container labeling to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information (see proposed § 201.405(d)(1)(viii)).

b. Side or back panel. The proposed rule would require the following information to be presented on the side or back panel of the Rx secondary container labeling and in the following order (see proposed § 201.405(d)(2)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information.

i. *Full prescribing information statement.* The proposed rule would require this section of the Rx secondary container labeling to include the statement: ''Before using this drug, read package insert for full prescribing information'' (see proposed § 201.405(d)(2)(i)). Because full prescribing information would not be provided on the Rx secondary container labeling, the purpose of the full prescribing information statement would be to remind the veterinarian to read full prescribing information before using the Rx new animal drug.

ii. ''*Dosage and Administration.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Dosage and Administration,'' followed by the ''Dosage and Administration'' section, as described in proposed § 201.405(a)(8) for full prescribing information (see proposed § 201.405(d)(2)(ii)).

iii. ''*Contraindications.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Contraindications,'' followed by the ''Contraindications'' section, as described in proposed § 201.405(a)(9) for full prescribing information (see proposed § 201.405(d)(2)(iii)).

iv. ''*Warnings and Precautions.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Warnings and Precautions,'' followed by the ''Warnings and Precautions'' section, as described in proposed § 201.405(a)(10) for full prescribing information (see proposed § 201.405(d)(2)(iv)).

v. ''*Active Ingredient*'' or ''*Active Ingredients.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and strength or concentration of each active ingredient, as described in proposed § 201.405(b)(2)(iii) for the Rx label (see proposed § 201.405(d)(2)(v)).

vi. ''*Inactive Ingredients.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Inactive Ingredients,'' followed by the established name of each inactive ingredient, as described in proposed § 201.405(a)(6)(viii) for full prescribing information (see proposed § 201.405(d)(2)(vi)).

vii. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage, handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information (see proposed § 201.405(d)(2)(vii)).

viii. *Name and place of business.* The proposed rule would require this section of the Rx secondary container labeling to identify the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information (see proposed § 201.405(d)(2)(viii)).

ix. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the Rx new animal drug within the secondary container. The proposed rule would also require this section of the Rx secondary container labeling to include the expiration date of the Rx new animal drug within the secondary container, in accordance with § 201.17. Alternatively, the proposed rule would allow for this section to refer to the location on the Rx secondary container labeling or secondary container where the lot or control number and expiration date are printed (see proposed § 201.405(d)(2)(ix)). As an example, if the lot number and expiration date are printed on the bottom flap of a secondary container, then the labeling may state in this section, ''See carton bottom flap for lot number and expiration date. However, in accordance with § 201.17, the proposed rule would allow an expiration date to be excluded from the Rx secondary container labeling or secondary container if the expiration date provided on the Rx label, Rx small label, or immediate container is easily legible through the secondary container.

x. ''*Revision Date.*'' The proposed rule would require this section of the Rx secondary container labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the Rx secondary container labeling, listing the month followed by the year (see proposed § 201.405(d)(2)(x)).

5. Shipping Labeling for Rx New Animal Drugs (Rx Shipping Labeling) (Proposed § 201.405(e))

The proposed rule would establish content and format requirements for the information on the shipping labeling for approved or conditionally approved Rx new animal drugs (Rx shipping labeling). As defined in proposed § 201.403, shipping labeling is associated with the outermost carton containing immediate containers, secondary containers, and/or multiple

unit (multi-unit) cartons of a new animal drug and intended for shipment, but not display, of the product. The proposed rule would require the Rx shipping labeling to include, among additional information, drug product identity, the manufacturer, packer, or distributor, and drug storage and handling conditions (see proposed § 201.405(e)). However, the Rx shipping labeling for controlled substances would not include information that would identify the drug, in accordance with § 1301.74(e), to guard against storage or in-transit losses due to theft or diversion.

The proposed rule would require the following information to be presented on the Rx shipping labeling and in the following order (see proposed § 201.405(e)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information.

a. Proprietary name of the finished drug product. The proposed rule would require this section of the Rx shipping labeling to include the proprietary name of the finished drug product (see proposed § 201.405(e)(1)). This section would be excluded from the Rx shipping labeling for a controlled substance.

b. Established name of the drug product. The proposed rule would require this section of the Rx shipping labeling to include the established name of the drug product (see proposed § 201.405(e)(2)). This section would be excluded from the Rx shipping labeling for a controlled substance.

c. Established name and strength or concentration of each active ingredient. The proposed rule would require this section of the Rx shipping labeling to provide the established name and strength or concentration of each active ingredient. This section would be excluded from the Rx shipping labeling for a controlled substance (see proposed § 201.405(e)(3)).

d. Conditional approval statement. For conditionally approved Rx new animal drugs, the proposed rule would require this section of the Rx shipping labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information (see proposed § 201.405(e)(4)). This section would be excluded from the Rx shipping labeling for a controlled substance.

e. ''*Net Contents.*'' The proposed rule would require this section of the Rx shipping labeling to have the heading ''Net Contents,'' followed by the contents of the shipping carton (see proposed § 201.405(e)(5)).

f. ''*Storage and Handling.*'' The proposed rule would require this section of the Rx shipping labeling to have the heading ''Storage and Handling,'' followed by drug storage information (see proposed § 201.405(e)(6)). Also, any handling information required for safe and effective use of the new animal drug would be included in this section. Information on disposal of the new animal drug would not be required to be included on the Rx shipping labeling.

g. NADA/ANADA approval statement. For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the Rx shipping labeling to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information (see proposed § 201.405(e)(7)). This section would be excluded from the Rx shipping labeling for a controlled substance.

h. Name and place of business. The proposed rule would require this section of the Rx shipping labeling to identify the name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information (see proposed § 201.405(e)(8)).

i. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the Rx shipping labeling to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number(s) and the expiration date(s) of the Rx new animal drug within the shipping carton (see proposed § 201.405(e)(9)). The shipping carton may contain more than one lot of the new animal drug, and therefore, more than one lot or control number and expiration date may be listed in this section of the Rx shipping labeling.

j. ''*Revision Date.*'' The proposed rule would require the last section of the Rx shipping labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the Rx shipping labeling, listing the month followed by the year (see proposed § 201.405(e)(10)).

6. Other Approved Labeling for Rx New Animal Drugs (Rx Other Approved Labeling) (Proposed § 201.405(f))

The proposed rule would establish content and format requirements for the information presented on other approved labeling for approved or conditionally approved Rx new animal drugs (Rx other approved labeling) (see proposed § 201.405(f)). Rx other approved labeling includes, but is not limited to, labeling on display cartons and multi-unit cartons (excluding shipping cartons), containing the immediate containers or the secondary containers of the Rx new animal drug.

The proposed rule would require the following information to be presented on the Rx other approved labeling and in the following order (see proposed § 201.405(f)). Unless otherwise indicated, this information would be the same as required by proposed § 201.405(a) for full prescribing information.

a. Proprietary name of the finished drug product. The proposed rule would require this section of the Rx other approved labeling to include the proprietary name of the finished drug product (see proposed § 201.405(f)(1)).

b. Established name of the drug product. The proposed rule would require this section of the Rx other approved labeling to include the established name of the drug product (see proposed § 201.405(f)(2)).

c. Established name and strength or concentration of each active ingredient. The proposed rule would require this section of the Rx other approved labeling to provide the established name and strength or concentration of each active ingredient (see proposed § 201.405(f)(3)).

d. Controlled substance symbol. The proposed rule would require this section of the Rx other approved labeling for controlled substances to include the controlled substance schedule symbol, in accordance with part 1302 designating the schedule for the drug substance (see proposed § 201.405(f)(4)).

e. Prescription statement. The proposed rule would require this section of the Rx other approved labeling to include the prescription statement, as described in proposed § 201.405(a)(2) for full prescribing information (see proposed § 201.405(f)(5)).

f. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the Rx other approved labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information (see proposed § 201.405(f)(6)).

g. Boxed warnings. For approved or conditionally approved Rx new animal drugs requiring boxed warnings, the proposed rule would require this section of the Rx other approved labeling to include the boxed warnings, as described in proposed § 201.405(a)(4) for full prescribing information (see proposed § 201.405(f)(7)).

h. Extralabel use prohibition statement. For approved new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of the Rx other approved labeling to include the extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information (see proposed § 201.405(f)(8)).

i. ''*Net Contents.*'' The proposed rule would require this section of the Rx other approved labeling to have the heading ''Net Contents,'' followed by the contents of the container to which the Rx other approved labeling applies (see proposed § 201.405(f)(9)).

j. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the Rx other approved labeling to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage, handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information (see proposed § 201.405(f)(10)).

k. NADA/ANADA approval statement. For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the Rx other approved labeling to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information (see proposed § 201.405(f)(11)).

l. Name and place of business. The proposed rule would require this section of the Rx other approved labeling to identify the name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information (see proposed § 201.405(f)(12)).

m. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the Rx other approved labeling to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the Rx new animal drug within the container to which the Rx other approved labeling applies. This section of the Rx other approved labeling would also be required to include the expiration date of the Rx new animal drug within the container to which the Rx other approved labeling applies, in accordance with § 201.17. In accordance with § 201.17, the proposed rule would allow an expiration date to be excluded from the Rx other approved labeling if the expiration date provided on containers within or their labeling is easily legible through the container to which the Rx other approved labeling applies (see proposed § 201.405(f)(13)).

n. ''*Revision Date.*'' The proposed rule would require the last section of the Rx other approved labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the Rx other approved labeling, listing the month followed by the year (see proposed § 201.405(f)(14)).

E. Content and Format for Over-The-Counter (OTC) New Animal Drug Labeling—Overview (Proposed § 201.407)

The proposed rules provides content and format requirements for all components of labeling for approved or conditionally approved OTC new animal drugs other than those for use in animal feeds that are subject to part 558 (see proposed § 201.407). Proposed § 201.409 would establish the content and format requirements for all components of labeling for approved or conditionally approved new animal drugs intended for use in animal feeds that are subject to part 558. OTC new animal drugs are new animal drugs that can be used without a prescription from a veterinarian. They are intended for use by the layperson, such as pet owners and livestock producers. In accordance with section 502(f) of the FD&C Act, OTC drugs must bear adequate directions for use on labeling. Adequate directions for use means directions under which the layperson can use a drug safely and for the purposes for which it is intended (see § 201.5).

The proposed rule would require that labeling sections or subsections that do not apply be omitted from the labeling for approved or conditionally approved OTC new animal drugs (see proposed § 201.407). For example, OTC new animal drugs approved or conditionally approved for use in non-food-producing animals (*e.g.,* cats, dogs) would not require the labeling subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods''.

FDA determines the final content of each applicable section of labeling during the review of each new animal drug as part of the approval process.

The proposed rule would identify the information that would be required to be included on the labeling component that would provide full product information for OTC new animal drugs in proposed § 201.407(a). Full product information for OTC new animal drugs would be similar in concept to full prescribing information for Rx new animal drugs in that it would include all information necessary for the safe and effective use of the OTC new animal drug. Thus, all approved or conditionally approved OTC new animal drugs would be required to provide a labeling component that includes full product information. If a package insert is provided with an OTC new animal drug, the proposed rule would require the package insert to include full product information. If only partial information is provided on a package insert, the user may mistakenly assume the package insert includes complete information on the safe and effective use of the drug when in fact it does not. If no package insert is provided with an OTC new animal drug, the secondary container labeling would be required to include full product information. If no package insert or secondary container labeling is provided with the OTC new animal drug, then full product information would need to be provided on the label (see proposed § 201.407(a)).

The label is the labeling component that appears on the immediate container, which is the container in contact with the drug. The proposed rule would establish content and format requirements for the label for an approved or conditionally approved OTC new animal drug that does not provide full product information (see proposed § 201.407(b)). The proposed rule would establish content and format requirements for a small label for an approved or conditionally approved OTC new animal drug that we determine lacks sufficient space to comply with proposed § 201.407(b) (see proposed § 201.407(c)).

For purposes of proposed subpart H, we would define a package insert for an approved or conditionally approved OTC new animal drug as a labeling component that contains full product information and is included with the immediate container or secondary container or is attached to the label (see proposed § 201.403). Where the package insert is attached to the label, which is sometimes referred to as, for example, ''extended labeling,'' ''onserts,'' or ''outserts,'' for purposes of proposed subpart H, the package insert providing full product information and attached to the label would need to comply with proposed § 201.407(a). The label would need to comply with proposed § 201.407(b) or (c), as applicable.

FDA considers the secondary container for a new animal drug to be the packaging that surrounds the immediate container. The proposed rule would establish content and format requirements for secondary container labeling for an approved or conditionally approved OTC new animal drug (see proposed § 201.407(d)). If a package insert is provided with an OTC new animal drug, then the secondary container labeling would be

required to comply with proposed § 201.407(d) and the package insert would be required to provide full product information to comply with proposed § 201.407(a). If no package insert is provided with an OTC new animal drug, the proposed rule would require full product information to appear on the secondary container labeling (see proposed § 201.407(a)).

In accordance with the definition of ''label'' in section 201(k) of the FD&C Act, information on the label must also appear on an outside container or wrapper of the retail package, if it exists, or be easily legible through the outside container or wrapper. For purposes of these proposed regulations, FDA considers the secondary container to be an ''outside container or wrapper of the retail package'' for new animal drugs. Therefore, if a secondary container exists, the proposed rule would require the secondary container labeling to include all information that would be on the label in accordance with proposed § 201.407(b) or (c), unless the information on the label is easily legible through the secondary container (see proposed § 201.407(a) or (d)).

Shipping labeling is associated with the outermost carton containing a new animal drug, which is intended for shipping, but not displaying the product. The proposed rule would establish content and format requirements for the shipping labeling of approved or conditionally approved OTC new animal drugs including a requirement that such shipping labeling identify the new animal drug, the manufacturer, and drug storage and handling information(see proposed § 201.407(e)).

Depending on how a sponsor intends to sell or display an approved or conditionally approved OTC new animal drug, there may be other containers such as display cartons and multiple unit (multi-unit) cartons that contain immediate containers or secondary containers. These containers may be packaged in shipping cartons. The proposed rule would establish content and format requirements for the labeling of these other containers for OTC new animal drugs (see proposed § 201.407(f)).

Labeling sections and subsections for OTC new animal drugs would not be numbered. Headings of sections and subsections that would be required to appear verbatim on labeling are identified in the proposed regulations in quotations. Similarly, certain other labeling text would be required to appear verbatim on labeling; this text is also identified in the proposed regulations in quotations.

The proposed rule would require the labeling of approved or conditionally approved OTC new animal drugs to comply with other applicable requirements in proposed subpart H (see proposed § 201.407).

1. Labeling Providing Full Product Information (Proposed § 201.407(a))

The proposed rule uses the term ''full prescribing information'' to identify all information necessary for the safe and effective use of approved or conditionally approved Rx new animal drugs, and the proposed regulations use that term for Rx new animal drugs. The concept of a component of labeling providing all information necessary for the safe and effective use of an approved or conditionally approved OTC new animal drug is equally important. FDA proposes that the term used for this information for approved or conditionally approved OTC new animal drugs would be ''full product information'' because OTC new animal drugs are not prescribed.

The proposed rule would establish content and format requirements for the component of labeling that provides full product information for approved or conditionally approved OTC new animal drugs (see proposed § 201.407(a)).

If a package insert is provided with an approved or conditionally approved OTC new animal drug, the proposed rule would require the package insert to include full product information (see proposed § 201.407(a)). If a package insert is provided with an approved or conditionally approved OTC new animal drug, the label would be required to comply with proposed § 201.407(b) or (c), and any secondary container labeling would be required to comply with proposed § 201.407(d).

If a package insert is not provided with an approved or conditionally approved OTC new animal drug, but a secondary container is provided, then the secondary container labeling would be required to provide full product information (see proposed § 201.407(a)). If full product information is provided on the secondary container labeling, in accordance with section 201(k) of the FD&C Act, proposed § 201.407(a) would allow the secondary container labeling to exclude any portions of full product information that would be required to appear on the label if such information is easily legible through the secondary container (see proposed § 201.407(a)).

If no package insert or secondary container is provided with an approved or conditionally approved OTC new animal drug, then the label would be required to include full product information (see proposed § 201.407(a)).

The proposed rule would require the following information to be presented in full product information for approved or conditionally approved OTC new animal drugs and in the following order. Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs.

a. Drug product identification. The proposed rule would require this section of full product information to include the proprietary name of the finished drug product and the established name of the drug product. If not included as part of the established name of the drug product, the route(s) of administration and dosage form of the finished drug product would be required to be included in this section as well (see proposed § 201.407(a)(1)(i) through (iv)).

The established name and strength or concentration of each active ingredient would also be required. The strength or concentration of each active ingredient would be allowed to be excluded from full product information provided on a package insert if the package insert applies to multiple strengths or concentrations for the same OTC new animal drug (see proposed § 201.407(a)(1)(v)).

If FDA determines that identifying the pharmacological class of an OTC new animal drug on labeling would be helpful in facilitating its safe and effective use, the proposed rule would require that the pharmacological class be included in this section of full product information (see proposed § 201.407(a)(1)(vi)).

b. Conditional approval statement. For conditionally approved OTC new animal drugs, the proposed rule would require this section of full product information to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for conditionally approved Rx new animal drugs (see proposed § 201.407(a)(2)).

c. ''*Uses.*'' This section of full product information would be required to have the heading ''Uses,'' followed by the approved or conditionally approved indication(s) and target animal(s) in the following format: ''For [indication(s)] in [target animal(s)]'' (see proposed § 201.407(a)(3)).

This section of full product information would be similar to the ''Indications for Use'' section of full prescribing information for Rx new animal drugs, as described in proposed

§ 201.405(a)(7). For OTC new animal drugs, the heading ''Uses'' may be better understood by the layperson and is consistent with the requirements for labeling of OTC human drugs (see § 201.66(c)(4)).

If FDA approves or conditionally approves an OTC new animal drug for use only under specific conditions, such as in conjunction with a specific diet, then the proposed rule would require that this information be specified in the ''Uses'' section of full product information (see proposed § 201.407(a)(3)(ii)).

FDA may require a statement in the ''Uses'' section of full product information describing the relative effectiveness of doses within the approved range of doses (see proposed § 201.407(a)(3)(iii)). This requirement primarily pertains to OTC new animal drugs that affect the structure or function of the body of an animal (section 201(g)(1)(C) of the FD&C Act) but are not intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (section 201(g)(1)(B) of the FD&C Act), *e.g.,* drugs that increase the rate of weight gain or feed efficiency in food-producing animals. For these new animal drugs, all doses within the range presented on the approved labeling must be effective for their intended use(s) (see 21 CFR 514.4(b)(2)(i)). For new animal drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, the lowest dose of the dose range must be effective for the intended use(s). However, the doses within the approved range do not need to be more effective than any other doses within the same range. For OTC new animal drugs approved for structure or function indications, if the highest approved dose(s) is not more effective compared to the next lower approved dose(s), the proposed rule would be able to require a statement in the ''Uses'' section to inform the user that a higher dose(s) is not more effective than the next lower dose(s).

For safety and/or effectiveness reasons, we may require a statement(s) in the ''Uses'' section of full product information identifying animals for which the OTC new animal drug has not been approved or conditionally approved (see proposed § 201.407(a)(3)(iv)).

d. Extralabel use statement. The proposed rule would require this section of full product information to include an extralabel use statement (see proposed § 201.407(a)(4)). In accordance with part 530, extralabel use of approved new animal drugs is not permitted except by or on the order of a licensed veterinarian and under the conditions described in that chapter. The required statement would be: ''It is a violation of Federal law to use this drug product other than as directed in the labeling or as directed by your veterinarian.'' It is important for the layperson to know when it is a violation of Federal law to use drugs in animals in an extralabel manner.

e. Extralabel use prohibition statement. For approved new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of full product information to include an extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information for Rx new animal drugs (see proposed § 201.407(a)(5)). Few OTC new animal drugs are prohibited from extralabel use under § 530.41. However, for the rare situation in which an approved OTC new animal drug is prohibited from extralabel use under § 530.41, this statement would be included in addition to the appropriate extralabel use statement that would be required by proposed § 201.407(a)(4).

f. ''*Description.*'' The proposed rule would require this section of full product information to have the heading ''Description,'' followed by a description of the new animal drug. The description would include the proprietary name of the finished drug product and established name of the drug product, and the route(s) of administration and dosage form if not included as part of the established name. The description would also include identifying characteristics of the dosage form, such as color, shape, coating, scoring, and imprinting. All approved and available strengths or concentrations of the new animal drug to which full product information applies would need to be identified in this section of full product information. If the drug product was sterile, this fact would also be identified in this section of full product information (see proposed § 201.407(a)(6)).

When inactive ingredients are provided on the labeling, the proposed rule would require they be listed in the ''Description'' section in decreasing order of predominance, by weight or concentration (see proposed § 201.407(a)(6)(viii)). We encourage sponsors to list all inactive ingredients on labeling to better inform users about the product.

g. ''*Warnings.*'' The proposed rule would require this section of full product information for all approved or conditionally approved OTC new animal drugs, and it would have the heading ''Warnings'' (see proposed § 201.407(a)(7)). This section of full product information would be similar to the ''Warnings and Precautions'' section proposed for full prescribing information for Rx new animal drugs, as described in proposed § 201.405(a)(10). However, ''precautions'' would be excluded from this section of full product information and instead be provided in the ''Additional Recommendations'' section of full product information, as described in proposed § 201.407(a)(8). A more complete explanation of the basis for this proposal is provided in the discussion of the ''Animal Safety Warnings'' subsection for OTC new animal drugs in proposed § 201.407(a)(7)(iii).

i. ''*Withdrawal Periods and Residue Warnings*'' or ''*Withdrawal Periods.*'' All OTC new animal drugs approved or conditionally approved for use in food-producing animals, would be required to have as the first subsection of the ''Warnings'' section of full product information a subsection with the heading ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods.'' This subsection would provide human food safety warnings, including milk discard times, withdrawal periods, and residue warning statements, as applicable to the new animal drug (see proposed § 201.407(a)(7)(i)). This subsection of full product information would be the same as described in proposed § 201.405(a)(10)(i) for full prescribing information for Rx new animal drugs.

ii. ''*User Safety Warnings.*'' The proposed rule would require this subsection of the ''Warnings'' section of full product information to have the heading ''User Safety Warnings,'' followed by the user safety warnings (see proposed § 201.407(a)(7)(ii)). This subsection of full product information would be the same as described in proposed § 201.405(a)(10)(ii) for full prescribing information for Rx new animal drugs.

iii. ''*Animal Safety Warnings.*'' For OTC new animal drugs with contraindications, target animal safety warnings that identify any serious adverse reaction or potential hazard to the target animal(s) associated with the use of the new animal drug, adverse reactions, or post-approval adverse drug experiences, the proposed rule would require this subsection of the ''Warnings'' section of full product information to have the heading ''Animal Safety Warnings,'' followed by the contraindications, target animal safety warnings, adverse reactions, and post-approval adverse drug experiences

(see proposed § 201.407(a)(7)(iii)). This proposed subsection of full product information would differ in some ways from the ''Animal Safety Warnings and Precautions'' subsection of full prescribing information proposed for Rx new animal drugs, as described in proposed § 201.405(a)(10)(iii), and these differences are the basis for the different proposed titles of these sections, *i.e.,* ''Warnings'' for OTC new animal drugs versus ''Warnings and Precautions'' for Rx new animal drugs.

The definition of ''precautions'' in proposed § 201.403 is ''any special care to be exercised for safe and effective use of the new animal drug. This may include recommended screening, monitoring, or diagnostic tests.'' Precautions related to Rx new animal drugs may include screening, special care and monitoring, or diagnostic tests intended to be performed by a veterinarian. Furthermore, precautions related to Rx new animal drugs are often related to, and difficult to distinguish from, target animal safety warnings. On the other hand, OTC new animal drugs do not require professional veterinary expertise to properly administer the drug, provide adequate post-treatment care, or monitor effects after use of the drug. For OTC new animal drugs, precautions provide additional recommendations to the layperson and are distinguishable from target animal safety warnings. For example, this may include information on when to administer the drug relative to feeding, or a recommendation to have a sound mastitis monitoring program before using the drug, etc. This advice is distinguishable from warnings for OTC new animal drugs. Therefore, for better clarity to the layperson, we propose that precautions for OTC new animal drugs not be included in the ''Animal Safety Warnings'' section of full product information and instead would be included in a separate section called ''Additional Recommendations,'' as described in proposed § 201.407(a)(8).

In addition, the ''Animal Safety Warnings'' subsection of full product information for OTC new animal drugs would differ from the ''Animal Safety Warnings and Precautions'' subsection of full prescribing information for Rx new animal drugs in terms of presentation of warning information. For OTC new animal drugs, all potential risks of the drug to the target animal would be included: contraindications, target animal safety warnings, adverse reactions, and post-approval adverse drug experiences as determined by FDA. For Rx new animal drugs, this information would be provided in different sections of full prescribing information.

For OTC new animal drugs, including all potential risks to the target animal in one subsection of full product information might be clearer for the layperson and increase the likelihood that all of the information would be read. Furthermore, identifying the risks to the target animal on labeling as ''contraindications,'' ''target animal safety warnings,'' ''adverse reactions,'' or ''post-approval adverse drug experience'' may be confusing to a layperson because they may not know the differences between the terms. The subsection heading ''Animal Safety Warnings'' would be understood by the layperson as meaning risks to the target animal. Therefore, the proposed rule would require that all risks to the target animal for OTC new animal drugs be simply identified as ''Animal Safety Warnings'' and placed in this subsection of full product information. All risk information listed under ''Animal Safety Warnings'' would be required to be listed in decreasing order of severity to emphasize the most critical risks to the target animal (see proposed § 201.407(a)(7)(iii)).

iv. ''*Environmental Warnings.*'' For new animal drugs having environmental warnings, the proposed rule would require this subsection of the ''Warnings'' section of full product information to have the heading ''Environmental Warnings,'' followed by the environmental warnings (see proposed § 201.407(a)(7)(iv)). This subsection of full product information would be the same as described in proposed § 201.405(a)(10)(iv) for full prescribing information for Rx new animal drugs.

v. ''*Other Warnings.*'' For OTC new animal drugs having warnings not more appropriately placed in other ''Warnings'' subsections, the proposed rule would require the last subsection of the ''Warnings'' section of full product information to have the heading ''Other Warnings,'' followed by those warnings (see proposed § 201.407(a)(7)(v)). This subsection of full product information would be the same as described in proposed § 201.405(a)(10)(v) for full prescribing information for Rx new animal drugs.

h. ''*Additional Recommendations.*'' For OTC new animal drugs having precautions, the proposed rule would require this section of full product information to have the heading ''Additional Recommendations,'' followed by all precautions (see proposed § 201.407(a)(8)). As described in its proposed definition, precautions include any special care to be exercised for safe and effective use of the new animal drug. As discussed with respect to proposed § 201.407(a)(7)(iii), regarding ''Animal Safety Warnings,'' precautions are distinguishable from target animal safety warnings for OTC new animal drugs. However, because the term ''precautions'' as intended by these proposed regulations may not be known or understood by the layperson, the title ''Additional Recommendations'' is proposed.

i. ''*Other Effects You May Notice.*'' For OTC new animal drugs that have effects on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences, and FDA determines these effects are required to be described on labeling, the proposed rule would require this section of full product information to have the heading ''Other Effects You May Notice,'' followed by a description of the effects (see proposed § 201.407(a)(9)). We consider this information important for owners of animals, and this information is currently provided on the labeling of some OTC new animal drugs.

For example, some OTC new animal drugs approved for increased rate of weight gain and/or feed efficiency in feedlot beef cattle have effects on the leanness or tenderness of the carcass of those animals. Similarly, OTC new animal drugs that increase milk production in dairy cows or the efficiency by which they produce milk may alter the fat percent content of the milk. These effects, which are currently described on the approved labeling for these products, are not considered negative health effects on the target animal nor are they of human food safety concern. However, these effects could be mistaken for symptoms of an underlying health problem in the target animal, such as poor nutritional status. For this reason, information of this type may be considered material under section 201(n) of the FD&C Act such that it would be required to be disclosed in the labeling for these products on the basis that such disclosures may preclude unnecessary concern and inappropriate medical treatment. Similarly, some topically applied OTC new animal drugs for companion animals might permanently (but harmlessly) alter the color of the fur at the application site. These types of potential effects that are not safety concerns, but rather provide important information to the layperson, would be included in this section of full product information.

j. ''*Directions.*'' The proposed rule would require this section of full

product information to have the heading ''Directions,'' followed by the directions for use of the OTC new animal drug for each indication and target animal (see proposed § 201.407(a)(10)). The corresponding section of full prescribing information for Rx new animal drugs would be called ''Dosage and Administration,'' as described in proposed § 201.405(a)(9). However, for OTC new animal drugs, the term ''Directions'' may be better understood by the layperson. In addition, the term ''Directions'' is also used in labeling of OTC human drugs (see § 201.66(c)(6)).

The ''Directions'' section of full product information is intentionally proposed for placement after the ''Warnings'' section. This is in contrast to the ''Dosage and Administration'' section in full prescribing information for Rx new animal drugs, which, except for ''Boxed Warnings,'' would be placed before ''Contraindications,'' ''Warnings and Precautions,'' ''Adverse Reactions,'' and other information about the effects of the drug. The intent in presenting ''Directions'' after the ''Warnings'' section in full product information for OTC new animal drugs is to increase the likelihood that the layperson will read the ''Warnings'' section before using the drug. This placement approach is similar to that used in labeling of OTC human drugs (see § 201.66(c)(6)).

The ''Directions'' section of full product information would be required to include information necessary for treatment of the animal with the OTC new animal drug in accordance with FDA approval or conditional approval, including route(s) of administration; specific site(s) of administration, if applicable; dose or dose range, intervals between doses, if applicable; and duration of treatment. For some injectable products, FDA may require a statement of maximum volume per injection site to facilitate the drug's safe and effective use, and the proposed rule would require this information to be included in this section of full product information. Other required dosage and administration information would be included in this section of full product information. See proposed § 201.407(a)(10).

k. ''*Net Contents.*'' The proposed rule would require this section of full product information, when presented on the label or the secondary container labeling, to have the heading ''Net Contents,'' followed by the contents of the immediate container, in accordance with § 201.62 (21 CFR 201.62), or the secondary container, respectively. The proposed rule would exclude a ''Net Contents'' section from package inserts (see proposed § 201.407(a)(11)).

l. ''*How Supplied.*'' The proposed rule would require this section of full product information to have the heading ''How Supplied,'' followed by information on available strengths, concentrations, and container sizes to which the labeling applies (see proposed § 201.407(a)(12)). This section of full product information would be the same as described in proposed § 201.405(a)(19) for full prescribing information for Rx new animal drugs.

m. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of full product information to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage information, as well as any required handling and drug disposal information (see proposed § 201.407(a)(13)). This section of full product information would be the same as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs.

n. ''*Questions/Comments?*'' The proposed rule would require this section of full product information to have the heading ''Questions/Comments?,'' followed by the sponsor's contact information for consumers to facilitate requesting additional information or to report suspected adverse drug experiences. FDA's contact information for voluntary reporting of adverse drug experiences for animal drugs would also be required (see proposed § 201.407(a)(14)). The ''Questions/Comments?'' section of full product information would be similar to the ''Contact Information'' section in proposed § 201.405(a)(12) for full prescribing information for Rx new animal drugs.

The ''Questions/Comments?'' heading might be clearer than ''Contact Information'' to the layperson using OTC new animal drugs. Furthermore, the heading ''Questions?'' or ''Questions or comments?'' is used for OTC human drug labeling (see § 201.66(c)(9)). Also, the phrase ''To report side effects, contact . . .'' is proposed for full product information for OTC new animal drugs rather than ''To report suspected adverse drug experiences, contact . . .,'' which is the phrase proposed for full prescribing information for Rx new animal drugs. The term ''side effects'' may be better understood by the layperson than the term ''suspected adverse drug experiences.'' Also, the term ''side effects'' may be used in labeling of OTC human drugs (see § 201.66(c)(5)(vii) (21 CFR 201.66(c)(5)(vii)).

The sponsor's contact information would be the name of the manufacturer, packer, or distributor, whichever is identified in the ''Name and place of business'' section of full product information (see proposed § 201.407(a)(16)). If more than one business is identified in the ''Name and place of business'' section of full product information, the drug sponsor would select the most appropriate of these businesses to use in the ''Questions/Comments?'' section to provide additional information about the OTC new animal drug and to contact regarding suspected adverse drug experiences.

The statements in this section of full product information would be required to be structured as follows: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report side effects, contact [insert name of business] at [insert business telephone number]. For additional information about reporting side effects for animal drugs, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Sponsors can search FDA's website or contact FDA by telephone to find the current FDA telephone number or web address for voluntary reporting of adverse drug experiences for animal drugs.

o. NADA/ANADA approval statement. For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of full product information to include an ''NADA approval statement'' or ''ANADA approval statement,'' respectively (see proposed § 201.407(a)(15)). This section of full product information would be the same as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs.

p. Name and place of business. The proposed rule would require this section of full product information to identify the name and place of business of the manufacturer, packer, or distributor (see proposed § 201.407(a)(16)). This section of full product information would be the same as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs.

q. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of full product information when provided on the secondary container labeling or the label. Package inserts are excluded from this requirement because they might apply to multiple lots of secondary or immediate containers of the OTC new animal drug. When full product

information is provided on the secondary container labeling or the label, this section would be required to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the OTC new animal drug within the secondary container or immediate container (see proposed § 201.407(a)(17)). A lot or control number would help us more easily to identify and trace back a specific lot of a product should a problem be reported to FDA. The proposed rule would also require this section to include the expiration date of the OTC new animal drug within the secondary container or immediate container, in accordance with § 201.17. An expiration date better ensures that the new animal drug would not be used after it expires.

Alternatively, the proposed rule would allow for this section of full product information to refer to the location on the secondary container labeling, secondary container, label, or immediate container where the lot or control number and expiration date are printed (see proposed § 201.407(a)(17)). As an example, if the lot number and expiration date are printed on the bottom flap of a secondary container, then the secondary container labeling may state in this section, ''See carton bottom flap for lot number and expiration date.'' However, if full product information is provided on the secondary container labeling, in accordance with § 201.17, the proposed rule would allow an expiration date to be excluded from the secondary container labeling or secondary container if the expiration date provided on the label or immediate container is easily legible through the secondary container.

r. ''*Revision Date.*'' The proposed rule would require this section of full product information to have the heading ''Revision Date,'' followed by the date of the most recent revision of the component of labeling that provides full product information, listing the month followed by the year (see proposed § 201.407(a)(18)). This information is important to ensure that the most current approved version of the labeling is being used.

2. OTC New Animal Drug Label Not Providing Full Product Information (OTC Label) (Proposed § 201.407(b))

The proposed rule would establish content and format requirements for the information presented on the label for approved or conditionally approved OTC new animal drugs (OTC label) where the label does not provide full product information (see proposed § 201.407(b)). As described previously in section V.E.1 regarding labeling providing full product information, the label for an OTC new animal drug would include full product information only if there is no package insert or secondary container labeling.

Proposed § 201.407(b) would apply to OTC labels that are of adequate size to contain the proposed required information per that paragraph, whereas proposed § 201.407(c) would apply to small labels for OTC new animal drugs that are not of adequate size to contain all the proposed required information in proposed § 201.407(b).

OTC new animal drugs labels to which § 201.407(b) would apply may consist of a single panel, a front panel and one side or back panel, or a front panel and multiple side and/or back panels, and the proposed rule would provide for such label designs (see proposed § 201.407(b)). For OTC labels with a front panel and one side or back panel, the proposed rule would require certain information for the front panel (see proposed § 201.407(b)(1)), and the side or back panel (see proposed § 201.407(b)(2)). For OTC labels consisting of a single panel, the proposed rule would require the information identified in proposed § 201.407(b)(1) followed by the information identified in proposed § 201.407(b)(2), in order, on the single panel. For OTC labels with a front panel and multiple side and/or back panels, the information identified in proposed § 201.407(b)(1) followed by the information identified in proposed § 201.407(b)(2) would be required in order, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information in proposed § 201.407(b)(1) and (2) was presented. In all instances, the information in proposed § 201.407(b)(2)(iii) and (iv), concerning active ingredients and inactive ingredients, would need to appear on the same panel.

a. Front panel. The proposed rule would require the following information to be presented on the front panel of the OTC label for an approved or conditionally approved OTC new animal drug and in the following order (see proposed § 201.407(b)(1)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs.

i. *Drug product identification.* The proposed rule would require this section of the OTC label to include drug product identification (see § 201.407(b)(1)(i)). This information may help the user to identify the product quickly and correctly and distinguish it from other, similar products. The information included in this section of the OTC label would include the same information as that in the drug product identification section of full product information, as described in proposed § 201.407(a)(1), in addition to a statement that the drug product is sterile, if applicable. Full product information would require a drug product identification section and ''Description'' section. Full product information for sterile OTC new animal drugs would be required to identify in the ''Description'' section that the drug is sterile. However, due to space limitations, no ''Description'' section is proposed for the OTC label. Instead, the drug product identification section of the OTC label for sterile OTC new animal drugs would be required to state that the drug product is sterile. See proposed § 201.407(b)(1)(i).

ii. *Conditional approval statement.* For conditionally approved new animal drugs, the proposed rule would require this section of the OTC label to include a conditional approval statement, as described in proposed § 201.405(a)(3)) for full prescribing information for Rx new animal drugs (see proposed § 201.407(b)(1)(ii)).

iii. ''*Uses.*'' The proposed rule would require this section of the OTC label to have the heading ''Uses,'' followed by the ''Uses'' section, as described in proposed § 201.407(a)(3) for full product information. If there is insufficient space on the OTC label for the complete ''Uses'' section as described in proposed § 201.407(a)(3), then the proposed rule would require the sponsor to include in this section of the OTC label the statement required in proposed § 201.407(a)(3)(i), *i.e.,* ''For [indication(s)] in [target animal(s)]''. If there is insufficient space on the OTC label for the statement in proposed § 201.407(a)(3)(i), then an abbreviated version of the statement would be required: ''For [abbreviated indication(s)] in [target animal(s)].'' In either situation where there is insufficient space on the OTC label for the complete ''Uses'' section as specified in proposed § 201.407(a)(3), the required statement would be followed by one of the following statements: ''See package insert for complete 'Uses'' if full product information is provided on a package insert; or ''See package labeling for

complete 'Uses''' if full product information is provided on the secondary container labeling. See proposed § 201.407(b)(1)(iii). The complete ''Uses'' section as described in proposed § 201.407(a)(3) may exceed the available space on the OTC label if, for example, it includes specific conditions of use (proposed § 201.407(a)(3)(ii)), a statement describing the relative effectiveness of doses within the approved range of doses (proposed § 201.407(a)(3)(iii)), animals for which the new animal drug is not approved or conditionally approved (proposed § 201.407(a)(3)(iv), and/or the indication(s) is lengthy and/or complex.

iv. *Extralabel use statement.* The proposed rule would require this section of the OTC label to include the extralabel use statement, as described in proposed § 201.407(a)(4) for full product information (see proposed § 201.407(b)(1)(iv)).

v. *Extralabel use prohibition statement.* For approved OTC new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of the OTC label to include the extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information for Rx new animal drugs (see proposed § 201.407(b)(1)(v)).

vi. ''*Withdrawal Periods and Residue Warnings*'' or ''*Withdrawal Periods.*'' For new animal drugs approved or conditionally approved for use in food-producing animals, the proposed rule would require this section of the OTC label to have the heading ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods,'' followed by all human food safety warnings, including milk discard times, withdrawal periods, and residue warning statements, as described in proposed § 201.405(a)(10)(i) for full prescribing information for Rx new animal drugs. If there is insufficient space on the front panel of the OTC labels with only a front panel and one side or back panel, the proposed rule would require this section to be provided on the side or back panel of the OTC label immediately following the complete product information statement specified in proposed § 201.407(b)(2)(i). See proposed § 201.407(b)(1)(vi).

vii. ''*Net Contents.*'' The proposed rule would require this section of the OTC label to have the heading ''Net Contents,'' followed by the contents of the immediate container, in accordance with § 201.62 (see proposed § 201.407(b)(1)(vii)).

viii. *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the OTC label to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.407(b)(1)(viii)).

b. Side or back panel. The proposed rule would require the following information to be presented on the side or back panel of the OTC label for an approved or conditionally approved OTC new animal drug in the following order (see proposed § 201.407(b)(2)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs.

i. *Complete product information statement.* The proposed rule would require this section of the OTC label to include one of two statements (see proposed § 201.407(b)(2)(i)). If full product information is provided on the package insert, the following statement would be used: ''Before using this drug, read package insert for complete product information.'' If full product information is provided on the secondary container labeling, the following statement would be used: ''Before using this drug, read package labeling for complete product information.'' Because full product information would not be provided on the OTC label, the purpose of the statements would be to remind the user to read full product information before using the OTC new animal drug.

ii. ''*Directions.*'' The proposed rule would require this section of the OTC label to have the heading ''Directions,'' followed by the ''Directions'' section as described in proposed § 201.407(a)(10) for full product information. If there is insufficient space on the OTC label for the complete requirements as specified in § 201.407(a)(10), or if it is necessary for additional information provided in full product information that is not provided on the OTC label to be read before administering the drug (*e.g.,* complete warnings and/or additional recommendations), then FDA may exclude this section from the OTC label (see proposed § 201.407(b)(2)(ii)). For example, if an OTC new animal drug is approved for multiple indications and/or target animals, there may be different target animal safety warnings or precautions associated with each indication and/or target animal. This information would be provided in full product information for the OTC new animal drug (in the ''Animal Safety Warnings'' subsection and ''Additional Recommendations'' section, respectively), but there may be insufficient space for it on the OTC label. Excluding the ''Directions'' section from the OTC label in this situation helps to ensure that the user would read full product information, which would include the ''Directions'' section as well as the ''Animal Safety Warnings'' subsection and ''Additional Recommendations'' section, before treating the animal. The user would also be reminded to read full product information before using the drug via the complete product information statement that would be required in the previous section of the OTC label by proposed § 201.407(b)(2)(i).

iii. ''*Active Ingredient*'' or ''*Active Ingredients.*'' The proposed rule would require this section of the OTC label to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and strength or concentration of each active ingredient (see proposed § 201.407(b)(2)(iii)).

iv. ''*Inactive Ingredients.*'' When inactive ingredients are provided on the OTC label, the proposed rule would require they be listed in the ''Inactive Ingredients'' section in decreasing order of predominance, by weight or concentration, as described in proposed § 201.405(a)(6)(viii) for full prescribing information for Rx new animal drugs (see proposed § 201.407(b)(2)(iv)).

v. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the OTC label to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage, handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs (see proposed § 201.407(b)(2)(v)).

vi. *Name and place of business.* The proposed rule would require this section of the OTC label to identify the name and place of business of the manufacturer, packer, or distributor, as required in section 502(b) of the FD&C Act (see proposed § 201.407(b)(2)(vi)).

vii. ''*Lot Number and Expiration Date*'' or ''*Lot Number*''. The proposed rule would require this section of the OTC label to have the heading ''Lot Number and Expiration Date'' or ''Lot Number,'' followed by the identifying lot or control number of the OTC new animal drug within the immediate container (see proposed § 201.407(b)(2)(vii)). A lot or control number would allow us more easily to identify and trace back a specific lot of a product should a problem be reported

to FDA. We would also require this section of the OTC label to include the expiration date of the OTC new animal drug within the immediate container, in accordance with § 201.17. An expiration date on the OTC label better ensures that the new animal drug would not be used after it expires. Alternatively, the proposed rule would allow for this section to refer to the location on the OTC label or immediate container where the lot or control number and expiration date are printed (see proposed § 201.407(b)(2)(vii)). As an example, if the lot number and expiration date are printed at the top of the immediate container, then the OTC label may state in this section, ''See top of container for lot number and expiration date.'' If the immediate container provides a single dose of the OTC new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, the proposed rule would not require an expiration date on the OTC label or immediate container, in accordance with § 201.17. Under such provision, this section of the OTC label would be required to be entitled ''Lot Number.''

viii. ''*Revision Date.*'' The proposed rule would require the last section of the OTC label to have the heading ''Revision Date,'' followed by the date of the most recent revision of the OTC label, listing the month followed by the year (see proposed § 201.407(b)(2)(viii)).

3. OTC New Animal Drug Small Label (OTC Small Label) (Proposed § 201.407(c))

The proposed rule would establish content and format requirements for the small label for OTC new animal drugs (OTC small label) where the label does not provide full product information (see proposed § 201.407(c)).

Some immediate containers, such as blister packs, pre-filled syringes, and small vials, are so small that only a minimal amount of information can be included on their label. The proposed rule would establish requirements for OTC small labels for approved or conditionally approved OTC new animal drugs (see proposed § 201.407(c)). We recognize that the size of the label is dependent upon the size of the immediate container. If an immediate container lacks sufficient space to contain a label that accommodates all of the information required by proposed § 201.407(a) or (b), the requirements of proposed § 201.407(c) would instead apply. We would ordinarily make this determination during the review of the new animal drug and its labeling, taking into consideration the readability and legibility of the information.

The proposed rule would require the following information to be presented on the OTC small label for an approved or conditionally approved OTC new animal drug and in the following order (see proposed § 201.407(c)).

a. Proprietary name of the finished drug product. The proposed rule would require this section of the OTC small label to include the proprietary name of the finished drug product (see proposed § 201.407(c)(1)). This requirement already exists for small labels for drugs in general in § 201.10(i)(1), but is repeated in these proposed regulations to include all requirements for labeling of approved or conditionally approved new animal drugs in proposed subpart H.

b. Established name of the drug product. The proposed rule would require this section of the OTC small label to include the established name of the drug product (see proposed § 201.407(c)(2)). This requirement already exists for small labels for drugs in general in § 201.10(i)(1), but is repeated in these proposed regulations to include all requirements for labeling of approved or conditionally approved new animal drugs in proposed subpart H.

c. Active ingredient(s). The proposed rule would require this section of the OTC small label to include the established name and strength or concentration of each active ingredient (see proposed § 201.407(c)(3)). This information should reduce the risk of miscalculating doses.

d. ''*For [target animal(s)] only.*'' The proposed rule would require this section of the OTC small label to include a brief listing of the approved target animal(s) as follows: ''For [target animal(s)] only'' (see proposed § 201.407(c)(4)). The brief listing of the approved target animal(s) is used in place of full ''Uses'' information because OTC small labels lack sufficient space. This listing would not require as much space on the OTC small label.

e. Complete product information statement. The proposed rule would require this section of the OTC small label to include one of two statements. If full product information is provided on the package insert, the following statement would be used: ''Read package insert for complete product information''. If full product information is provided on the secondary container labeling, the following statement would be used: ''Read package labeling for complete product information.'' See proposed § 201.407(c)(5). Because full product information would not be provided on the OTC small label, the purpose of the statements would be to remind the user to read full product information before using the OTC new animal drug.

f. ''*Net Contents.*'' The proposed rule would require this section of the OTC small label to have the heading ''Net Contents,'' followed by the contents of the immediate container, in accordance with § 201.62 (see proposed § 201.407(c)(6)).

g. Name and place of business. The proposed rule would require this section of the OTC small label to identify the name and place of business of the manufacturer, packer, or distributor, as required in section 502(b) of the FD&C Act (see proposed § 201.407(c)(7)).

h. ''*Lot, Exp. and Storage*'' *or* ''*Lot and Storage.*'' The proposed rule would require this section of the OTC small label to have the heading ''Lot, Exp. and Storage'' or ''Lot and Storage,'' followed by the identifying lot or control number of the OTC new animal drug within the immediate container. A lot or control number would allow FDA more easily to identify and trace back a specific lot of a product should a problem be reported to FDA. The proposed rule would also require this section of the OTC small label to include the expiration date of the OTC new animal drug within the immediate container, in accordance with § 201.17. An expiration date on the OTC small label better ensures that the new animal drug would not be used after it expires.

The proposed rule would also require this section of the OTC small label to include and drug storage information for the new animal drug (see proposed § 201.407(c)(8)). Storage information is necessary to maintain potency of the drug before its expiration date. Requiring this information on the OTC small label is needed for safe and effective use of new animal drugs. If the immediate container provides a single dose of the OTC new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, the proposed rule would not require an expiration date on the immediate container or OTC small label, in accordance with § 201.17, in which case this section of the OTC small label would be required to be entitled ''Lot and Storage.''

i. ''*Revision Date.*'' The proposed rule would require this section of the OTC small label to have the heading ''Revision Date,'' followed by the date of the most recent revision of the OTC small label, listing the month followed

by the year (see proposed § 201.407(c)(9)).

4. Labeling for Secondary Containers for OTC New Animal Drugs That Include a Package Insert (OTC Secondary Container Labeling) (Proposed § 201.407(d))

The proposed rule would establish content and format requirements for the information on the labeling for secondary containers of approved or conditionally approved OTC new animal drugs that include a package insert (OTC secondary container labeling) (see proposed § 201.407(d)). In this situation, the package insert would be required by the proposed regulations to include full product information as in proposed § 201.407(a)).

In accordance with section 201(k) of the FD&C Act, the OTC secondary container labeling could exclude any information described in proposed § 201.407(d) that would be required to appear on the OTC label or OTC small label (see proposed § 201.407(b) or (c), respectively) if such information on the OTC label or OTC small label was easily legible through the secondary container.

The OTC secondary container labeling to which proposed § 201.407(d) would apply may consist of a front panel and one side or back panel, or a front panel and multiple side and/or back panels. Proposed § 201.407(d) would provide for such OTC secondary container labeling designs. For OTC secondary container labeling with a front panel and one side or back panel, proposed § 201.407(d)(1) would provide required information for the front panel, and proposed § 201.407(d)(2) would provide required information for the side or back panel. For OTC secondary container labeling with a front panel and multiple side and/or back panels, the information identified in proposed § 201.407(d)(1) followed by the information identified in proposed § 201.407(d)(2) would be required in order, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information in proposed § 201.407(d)(1) and (2) was presented. In all instances, the information proposed in § 201.407(d)(2)(iv) and (v), concerning active ingredients and inactive ingredients, would need to appear on the same panel.

a. Front panel. The proposed rule would require the following information to be presented on the front panel of the OTC secondary container labeling and in the following order (see proposed § 201.407(d)(1)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs.

i. *Drug product identification.* The proposed rule would require this section of the OTC secondary container labeling to include drug product identification (see proposed § 201.407(d)(1)(i)). The information would be the same as that included in the drug product identification section for full product information, as described in proposed § 201.407(a)(1), and would also identify if the drug product is sterile. Full product information would require a drug product identification section and a ''Description'' section. Full product information for sterile OTC new animal drugs would be required to identify in the ''Description'' section that the drug is sterile. However, due to space limitations, no ''Description'' section would be required on the OTC secondary container labeling. Instead, the drug product identification section of the OTC secondary container labeling for sterile OTC new animal drugs would be required to state that the drug is sterile.

ii. *Conditional approval statement.* For conditionally approved OTC new animal drugs, the proposed rule would require this section of the OTC secondary container labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.407(d)(1)(ii)).

iii. ''*Uses.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Uses,'' followed by the ''Uses'' section, as described in proposed § 201.407(a)(3) for full product information (see proposed § 201.407(d)(1)(iii)).

iv. *Extralabel use statement.* The proposed rule would require this section of the OTC secondary container labeling to include the extralabel use statement as described in proposed § 201.407(a)(4) for full product information (see proposed § 201.407(d)(1)(iv)).

v. *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of the OTC secondary container labeling to include the extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information for Rx new animal drugs (see proposed § 201.407(d)(1)(v)).

vi. ''*Net Contents.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Net Contents,'' followed by the contents of the secondary container (see proposed § 201.407(d)(1)(vi)).

vii. *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the OTC secondary container labeling to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.407(d)(1)(vii)).

b. Side or back panel. The proposed rule would require the following information to be presented on the side or back panel of the OTC secondary container labeling and in the following order (see proposed § 201.407(d)(2)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally OTC new animal drugs.

i. *Complete product information statement.* The proposed rule would require this section of the OTC secondary container labeling to include the statement, ''Before using this drug, read package insert for complete product information'' (see proposed § 201.407(d)(2)(i)). Because full product information would not be provided on the OTC secondary container labeling, the purpose of the Complete product information statement would be to remind the user to read full product information before using the OTC new animal drug.

ii. ''*Directions.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Directions,'' followed by the ''Directions'' section, as described in proposed § 201.407(a)(10) for full product information (see proposed § 201.407(d)(2)(ii)).

iii. ''*Warnings.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Warnings,'' followed by the ''Warnings'' section, as described in proposed § 201.407(a)(7) for full product information (see proposed § 201.407(d)(2)(iii)).

iv. ''*Active Ingredient*'' or ''*Active Ingredients.*'' The proposed rule would require this section of the OTC

secondary container labeling to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and strength or concentration of each active ingredient, as described in proposed § 201.407(b)(2)(iii) for the OTC label (see proposed § 201.407(d)(2)(iv)).

v. ''*Inactive Ingredients.*'' When inactive ingredients are provided on the OTC secondary container labeling, the proposed rule would require they be listed in the ''Inactive Ingredients'' section by their established name in decreasing order of predominance, by weight or concentration, as described in proposed § 201.405(a)(6)(viii) (see proposed § 201.407(d)(2)(v)).

vi. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage, handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx animal drugs (see proposed § 201.407(d)(2)(vi)).

vii. *Name and place of business.* The proposed rule would require this section of the OTC secondary container labeling to identify the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information for Rx animal drugs (see proposed § 201.407(d)(2)(vii)).

viii. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the OTC new animal drug within the secondary container. The proposed rule would also require this section of the OTC secondary container labeling to include the expiration date of the OTC new animal drug within the secondary container, in accordance with § 201.17. Alternatively, the proposed rule would allow for this section to refer to the location on the OTC secondary container labeling or secondary container where the lot or control number and expiration date are printed (see proposed § 201.407(d)(2)(viii)). As an example, if the lot number and expiration date are printed on the bottom flap of a secondary container, then the labeling may state in this section, ''See carton bottom flap for lot number and expiration date.'' However, in accordance with § 201.17, the proposed rule would allow an expiration date to be excluded from the OTC secondary container labeling or secondary container if the expiration date provided on the OTC label, OTC small label, or immediate container is easily legible through the secondary container.

ix. ''*Revision Date.*'' The proposed rule would require this section of the OTC secondary container labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the OTC secondary container labeling, listing the month followed by the year (see proposed § 201.407(d)(2)(ix)).

5. Shipping Labeling for OTC New Animal Drugs (OTC Shipping Labeling) (Proposed § 201.407(e)

The proposed rule would establish content and format requirements for the information on the shipping labeling for approved or conditionally approved OTC new animal drugs (OTC shipping labeling). As defined in proposed § 201.403, shipping labeling is associated with the outermost carton containing immediate containers, secondary containers, and/or multiple unit (multi-unit) cartons of a new animal drug and intended for shipment, but not display, of the product. The proposed rule would require the OTC shipping labeling to include, among additional information, drug product identity, the manufacturer, packer, or distributor, and drug storage and handling conditions. See proposed § 201.407(e).

The proposed rule would require the following information to be presented on the OTC shipping labeling and in the following order (see proposed § 201.407(e)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs.

a. Proprietary name of the finished drug product. The proposed rule would require this section of the OTC shipping labeling to include the proprietary name of the finished drug product (see proposed § 201.407(e)(1)).

b. Established name of the drug product. The proposed rule would require this section of the OTC shipping labeling to include the established name of the drug product (see proposed § 201.407(e)(2)).

c. Established name and strength or concentration of each active ingredient. The proposed rule would require this section of the OTC shipping labeling provide the established name and strength or concentration of each active ingredient (see proposed § 201.407(e)(3)).

d. Conditional approval statement. For conditionally approved OTC new animal drugs, the proposed rule would require this section of the OTC shipping labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.407(e)(4)).

e. ''*Net Contents.*'' The proposed rule would require this section of the OTC shipping labeling to have the heading ''Net Contents,'' followed by the contents of the shipping carton (see proposed § 201.407(e)(5)).

f. ''*Storage and Handling.*'' The proposed rule would require this section of the OTC shipping labeling to have the heading ''Storage and Handling,'' followed by drug storage information (see proposed § 201.407(e)(6)). Also, any handling information required for safe and effective use of the new animal drug would be included in this section. Information on disposal of the new animal drug would not be required to be included on the OTC shipping labeling.

g. NADA/ANADA approval statement. For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the OTC shipping labeling to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.407(e)(7)).

h. Name and place of business. The proposed rule would require this section of the OTC shipping labeling to identify the name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs (see proposed § 201.407(e)(8)).

i. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the OTC shipping labeling to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number(s) and the expiration date(s) of the OTC new animal drug within the shipping carton (see proposed § 201.407(e)(9)). The shipping carton may contain more than one lot of the OTC new animal drug, and therefore, more than one lot or control number and expiration date may be listed in this section of the OTC shipping labeling.

j. ''*Revision Date.*'' The proposed rule would require the last section of the OTC shipping labeling to have the heading ''Revision Date,'' followed by

the date of the most recent revision of the OTC shipping labeling, listing the month followed by the year (see proposed § 201.407(e)(10)).

6. Other Approved Labeling for OTC New Animal Drugs (OTC Other Approved Labeling) (Proposed § 201.407(f))

The proposed rule would establish content and format requirements for the information presented on other approved labeling for approved or conditionally approved OTC new animal drugs (OTC other approved labeling) (see proposed § 201.407(f)). OTC other approved labeling includes, but is not limited to, labeling on display cartons and multi-unit cartons (excluding shipping cartons), containing the immediate containers or the secondary containers of the OTC new animal drug.

The proposed rule would require the following information to be presented on the OTC other approved labeling and in the following order (see proposed § 201.407(f)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs.

a. Proprietary name of the finished drug product. The proposed rule would require this section of the OTC other approved labeling to include the proprietary name of the finished drug product (see proposed § 201.407(f)(1)).

b. Established name of the drug product. The proposed rule would require this section of the OTC other approved labeling to include the established name of the drug product (see proposed § 201.407(f)(2)).

c. Established name and strength or concentration of each active ingredient. The proposed rule would require this section of the OTC other approved labeling to provide the established name and strength or concentration of each active ingredient (see proposed § 201.407(f)(3)).

d. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the OTC other approved labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx animal drugs (see proposed § 201.407(f)(4)).

e. Extralabel use statement. The proposed rule would require this section of the OTC other approved labeling to include the extralabel use statement as described in proposed § 201.407(a)(4) for full product information (see proposed § 201.407(f)(5)).

f. Extralabel use prohibition statement. For approved new animal drugs prohibited from extralabel use, in accordance with § 530.41, the proposed rule would require this section of the OTC other approved labeling to include the extralabel use prohibition statement, as described in proposed § 201.405(a)(5) for full prescribing information for Rx new animal drugs (see proposed § 201.407(f)(6)).

g. ''*Net Contents.*'' The proposed rule would require this section of the OTC other approved labeling to have the heading ''Net Contents,'' followed by the contents of the container to which the OTC other approved labeling applies (see proposed § 201.407(f)(7)).

h. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the OTC other approved labeling to have the heading ''Storage, Handling, and Disposal,'' followed by drug storage, handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs (see proposed § 201.407(f)(8)).

i. NADA/ANADA approval statement. For approved new animal drugs or approved generic new animal drugs, the proposed rule would require this section of the OTC other approved labeling to include the NADA or ANADA approval statement, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.407(f)(9)).

j. Name and place of business. The proposed rule would require this section of the OTC other approved labeling to identify the name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs (see proposed § 201.407(f)(10)).

k. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the OTC other approved labeling to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the OTC new animal drug within the container to which the OTC other approved labeling applies. This section of the OTC other approved labeling would also be required to include the expiration date of the OTC new animal drug within the container to which the OTC other approved labeling applies, in accordance with § 201.17. In accordance with § 201.17, the proposed rule would allow an expiration date to be excluded from the OTC other approved labeling if the expiration date provided on containers within or their labeling is easily legible through the container to which the OTC other approved labeling applies (see proposed § 201.407(f)(11)).

l. ''*Revision Date.*'' The proposed rule would require the last section of the OTC other approved labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the OTC other approved labeling, listing the month followed by the year (see proposed § 201.405(f)(12)).

F. Content and Format of Labeling for New Animal Drugs for Use in Animal Feeds—Overview (Proposed § 201.409)

The proposed rule provides content and format requirements for all components of labeling for approved or conditionally approved new animal drugs for use in animal feeds and that are subject to part 558, including VFD drugs. New animal drugs for use in animal feeds are approved in accordance with section 512 of the FD&C Act or conditionally approved in accordance with section 571 of the FD&C Act (see proposed § 201.409). Most combination new animal drugs are currently approved for use in animal feeds or drinking water in accordance with section 512(d)(4) of the FD&C Act. The majority of new animal drugs approved or conditionally approved for use in animal feeds are intended for use in food-producing animals and to be fed to multiple animals at one time.

As described above, proposed § 201.405 (''Content and format for prescription (Rx) new animal drug labeling'') would not apply to approved or conditionally approved new animal drugs intended for use in or on animal feeds under the professional supervision of a licensed veterinarian because, in accordance with section 504(a) of the FD&C Act, such drugs are approved or conditionally approved as VFD drugs. The proposed rule would establish the content and format requirements for all components of labeling for approved or conditionally approved new animal drugs intended for use in animal feeds that are subject to part 558, including VFD drugs (see proposed § 201.409).

The proposed rule would require that labeling sections or subsections that do not apply be omitted from the labeling for approved or conditionally approved new animal drugs for use in animal feeds (see proposed § 201.409). For example, new animal drugs approved or conditionally approved for use in animal feeds that are not VFD drugs would not require a VFD cautionary statement section.

FDA determines the final content of each applicable section of labeling during the review of each new animal drug as part of the approval process.

Sponsors of new animal drugs for use in animal feeds often submit an application for approval or conditional approval of a ''Type A medicated article,'' which is a concentrated form of the drug intended solely for use in the manufacture of another Type A medicated article or medicated feeds (*i.e.,* ''Type B medicated feeds'' and/or ''Type C medicated feeds,'' see below), The Type A medicated article consists of a new animal drug(s), with or without a carrier, with or without inactive ingredients (see § 558.3(b)(2) (21 CFR 558.3(b)(2))).

Type B medicated feed is intended solely for the manufacture of other medicated feeds (Type B or Type C). It serves as an intermediate medicated feed not approved for feeding to the target animals. It is manufactured by diluting a Type A medicated article or another Type B medicated feed with non-medicated feed, and at least 25 percent of its weight is from nutritional ingredients (see § 558.3(b)(3)). The maximum approvable concentrations of new animal drugs in Type B medicated feeds must be established in accordance with § 558.3(b)(3). The specific maximum concentrations for approved new animal drugs in Type B medicated feeds are listed in § 558.4(d).

Type C medicated feed is fed directly to target animals. It may also be used in the manufacture of another Type C medicated feed. When fed directly to target animals, it is intended to be the animals' complete feed or part of their total diet. It is manufactured by diluting a Type A medicated article, a Type B medicated feed, or another Type C medicated feed with non-medicated feed, and it contains a substantial quantity of nutritional ingredients (see § 558.3(b)(4)).

Labeling for new animal drugs intended for use in feed must be included in the new animal drug application (see § 514.1(b)(3)(v)). Such labeling may include a Type A medicated article label, representative labeling for Type B and Type C medicated feeds containing the new animal drug, proprietary labeling for Type B or Type C medicated feeds, and/or other approved labeling associated with the Type A medicated article.

Proposed § 201.409(a) identifies the information that would be required to be included on Type A medicated article labels. A Type A medicated article label is on the immediate container, which is typically a bag. The Type A medicated article label provides all information necessary for the safe and effective use of the new animal drug.

Similar to the labeling of other approved or conditionally approved new animal drugs, the Type A medicated article label includes product and manufacturer, packer or distributor identification, approved or conditionally approved indications for use, warnings, and directions for use. In addition, the directions for use for a Type A medicated article must include mixing directions for the manufacture of medicated feeds from the Type A medicated article, as well as feeding directions for the finished Type C medicated feeds manufactured from the Type A medicated article (see § 514.1(b)(3)(v)(*a*)).

Proposed § 201.409(b) and (c) identify the information that would be required to be included on representative Type B medicated feed labeling and representative Type C medicated feed labeling, respectively. Sponsors of a Type A medicated article must include in their application representative labeling proposed for use in manufacturing Type B and Type C medicated feeds containing the new animal drug (see § 514.1(b)(3)(v)(*b*)). FDA approves or conditionally approves the use of the Type A medicated article to manufacture Type B and Type C medicated feeds and also approves or conditionally approves the Type A medicated article label and the representative labeling for the Type B and Type C medicated feeds.

Representative Type B and Type C medicated feed labeling is template labeling approved by FDA as part of an NADA or CNADA for a Type A medicated article. Representative Type B and Type C medicated feed labeling approved in the NADA or CNADA provide feed mills the minimal information that must be included on the final printed labels prepared for the respective Type B and Type C medicated feeds manufactured containing the Type A medicated article to provide for safe and effective use of the new animal drug for its approved or conditionally approved indication(s) for use. FDA also uses the term ''Blue Bird labels'' to refer to representative Type B and Type C medicated feed labeling (see 64 FR 63195 at 63197, November 19, 1999).

Because the approved or conditionally approved Type C medicated feeds will be used as part of the diet, or as the complete diet, of the target animals, the representative Type B and Type C medicated labeling also provide for the nutritional requirements or content to be specified in the final printed labels for the medicated feed.

If a final printed label for a Type B or Type C medicated feed fails to conform to the approved representative Type B or Type C medicated feed labeling, the medicated feed will be deemed unsafe, in accordance with section 512(a)(2) of the FD&C Act, and adulterated, in accordance with section 501(a)(6) of the FD&C Act.

If Type A medicated article(s) are approved or conditionally approved for more than one indication and/or target animal, the concentration of the new animal drug(s) may differ in the medicated feed approved or conditionally approved for these indication(s) and/or target animal(s). Also, the nutritional requirements or content specified in the representative labeling for the medicated feeds may vary for different target animals. These applications for Type A medicated articles may include representative Type B medicated feed labeling and representative Type C medicated feed labeling for each of the approved uses.

Some Type A medicated articles are approved or conditionally approved to be manufactured only directly into Type C medicated feeds. In addition to the Type A medicated article label, the applications for these Type A medicated articles must provide representative labeling only for Type C medicated feeds.

If new animal drugs for use in animal feeds or drinking water are approved for combination use, in accordance with section 512(d)(4) of the FD&C Act, these ''combination new animal drugs'' generally provide for more than one approved Type A medicated article to be mixed into medicated feed or drinking water for the approved target animal. The only labeling approved for such combination new animal drugs is representative labeling for the medicated feeds that combines information from the representative labeling of each individual Type A medicated article. Combination new animal drugs exclude conditionally approved drugs subject to section 571 of the FD&C Act. Section 512(d)(4) of the FD&C Act was amended as part of the MUMS Act of 2004 to clarify that only products approved under section 512(b)(1) of the FD&C Act can be used in new animal drug combinations.

Proposed § 201.409(f) identifies the information that would be required to be included on other approved labeling for Type A medicated articles. Other approved labeling for Type A medicated articles may include shipping labeling associated with shipment of bags of the Type A medicated article.

Proposed § 201.409(d) identifies the information that would be required to be included on proprietary Type B medicated feed labels. In addition to approving or conditionally approving applications for Type A medicated articles, FDA may also approve or conditionally approve applications for proprietary final formulations of Type B medicated feeds. A proprietary Type B medicated feed is intended solely for the manufacture of Type C medicated feeds or other Type B medicated feeds and is not approved or conditionally approved for feeding to the target animals. For some proprietary Type B medicated feeds, the formulation and labeling are approved in an NADA or CNADA. In other situations, the underlying data and labeling for the proprietary Type B medicated feed to support the approved uses are maintained in a VMF. For example, this would include situations in which a proprietary Type B medicated feed is manufactured via modification to an approved formulation published in the CFR or where a feed manufacturer creates its own proprietary formulation. The application for a proprietary Type B medicated feed will include the proprietary label for the final Type B medicated feed and representative Type C medicated feed labeling that directs the preparation of final printed labels for Type C medicated feeds manufactured from the proprietary Type B medicated feed. Applications for proprietary final formulations of Type B medicated feeds will not include a Type A medicated article label.

Proposed § 201.409(e) identifies the information that would be required to be included on proprietary Type C medicated feed labels. FDA may also approve or conditionally approve applications for proprietary final formulations of Type C medicated feeds. For some proprietary Type C medicated feeds, the formulation and labeling are approved in an NADA or CNADA. In other situations, the underlying data and labeling for the proprietary Type C medicated feed to support the approved uses are maintained in a VMF. For example, this would include situations in which a proprietary Type C medicated feed is manufactured via modification to an approved formulation published in the CFR or where a feed manufacturer creates its own proprietary formulation. The application for a proprietary Type C medicated feed will include the proprietary label for the final Type C medicated feed.

Prior to the enactment of the ADAA, new animal drugs for use in animal feeds were approved almost exclusively for OTC use. The ADAA allowed for approval or conditional approval of a new type of new animal drugs for use in or on animal feeds called the ''veterinary feed directive drug'' (VFD drug). Although not identical, the use of VFD drugs shares similar requirements to the use of Rx new animal drugs.

A veterinarian may only issue a VFD for use in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements (see § 558.6(b) (21 CFR 558.6(b))). Information that must be included in a VFD is in § 558.6(b).

In accordance with § 558.6(a)(6), the following cautionary statement must appear on all labeling and advertising associated with a VFD drug: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.''

Some sections of proposed § 201.409 are patterned after sections of proposed § 201.405 for labeling of Rx new animal drugs or proposed § 201.407 for labeling of OTC new animal drugs. These sections include the conditional approval statement or NADA/ANADA approval statement, indications for use, warnings, and other information associated with the effects of the new animal drug. Other sections of proposed § 201.409 are uniquely associated with medicated articles and feeds, such as mixing directions, feeding directions, and information on nutritional content.

The labeling sections and subsections for new animal drugs for use in animal feeds would not be numbered. Headings of sections and subsections that would be required to appear verbatim on labeling are identified in the proposed regulations in quotations. Similarly, certain other labeling text would be required to appear verbatim on labeling; this text is also identified in the proposed regulations in quotations.

The proposed rule would require the labeling of approved or conditionally approved new animal drugs for use in animal feeds and that are subject to part 558 of this chapter to comply with other applicable requirements in proposed subpart H (see proposed § 201.409).

1. Type A Medicated Article Label (Proposed § 201.409(a))

The proposed rule would establish content and format requirements for the Type A medicated article label for new animal drugs approved or conditionally approved for use in animal feeds (see proposed § 201.409(a)). A Type A medicated article is a concentrated form of the new animal drug intended solely for use in the manufacture of another Type A medicated article or Type B medicated feeds and/or Type C medicated feeds. As defined in § 558.3(b)(2), a Type A medicated article consists of a new animal drug(s), with or without a carrier, with or without inactive ingredients. A Type A medicated article label is on the immediate container, which is typically a bag.

The Type A medicated article label provides all information necessary for the safe and effective use of the new animal drug.

The proposed rule would require the following information to be presented on the Type A medicated article label for an approved or conditionally approved new animal drug and in the following order (see proposed § 201.409(a)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs or proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs.

a. Type A medicated article identification. The proposed rule would require this section of the Type A medicated article label to include the proprietary name, the established name of the Type A medicated article, and the phrase ''Type A medicated article'' or ''Type A liquid medicated article,'' as applicable, if not included as part of the established name of the Type A medicated article (see proposed § 201.409(a)(1)).

b. VFD cautionary statement. For VFD new animal drugs, the proposed rule would require this section of the Type A medicated article label to include the following cautionary statement, in accordance with § 558.6(a)(6): ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.'' This statement would be required to be displayed prominently and conspicuously on the Type A medicated article label (see proposed § 201.409(a)(2)).

c. ''*For further manufacturing only.*'' The proposed rule would require this section of the Type A medicated label to include the statement, ''For further manufacturing only'' (see proposed § 201.409(a)(3)). This statement would indicate that the Type A medicated article can only be used to manufacture another Type A medicated article or a medicated feed. A Type A medicated article cannot be fed directly to animals.

d. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the Type A medicated article label to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for conditionally approved Rx new animal drugs (see proposed § 201.409(a)(4)).

e. ''*Indications for Use.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Indications for Use,'' followed by the approved or conditionally approved indication(s) and target animal(s), as described in proposed § 201.407(a)(3) for full product information for OTC new animal drugs, with the exception of the heading of the section (see proposed § 201.409(a)(5)).

f. Extralabel use statement. The proposed rule would require this section of the Type A medicated article label to include an extralabel use statement (see proposed § 201.409(a)(6)). Extralabel use of an approved new animal drug or human drug in or on an animal feed is not permitted (see section 512(a)(4) of the FD&C Act and part 530). The required statement would be: ''It is a violation of Federal law to use other than as directed in the labeling.'' It is important for the layperson and veterinarian to know that it is a violation of Federal law to use new animal drugs in or on animal feeds in an extralabel manner.

g. ''*Active Ingredient*'' *or* ''*Active Ingredients.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and concentration of each active ingredient in the Type A medicated article (see proposed § 201.409(a)(7)). If the Type A medicated article contains one active ingredient, the proposed rule would require this section of the Type A medicated article label to be entitled ''Active Ingredient.'' If the Type A medicated article contains more than one active ingredient, the proposed rule would require this section of the Type A medicated article label to be entitled ''Active Ingredients.'' Including the concentration of the active ingredient(s) is critical so that feed manufacturers can properly mix Type B and C medicated feeds from the Type A medicated article with the approved concentration(s) of the active ingredient(s).

h. ''*Inactive Ingredients.*'' When inactive ingredients are provided on the Type A medicated article label, the proposed rule would require they be listed in the ''Inactive Ingredients'' section in decreasing order of predominance, by weight or concentration, as described in proposed § 201.405(a)(6)(viii) for full prescribing information for Rx new animal drugs (see proposed § 201.409(a)(8)).

i. ''*Directions.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Directions,'' followed by the directions for use of the Type A medicated article (see proposed § 201.409(a)(9)). The ''Directions'' section of the Type A medicated article label would include three subsections.

i. ''*Approved Concentration(s) of [Active Ingredient or Active Moiety] in Type C Medicated Feeds.*'' The proposed rule would require the first subsection of the ''Directions'' section of the Type A medicated article label to have the heading ''Approved Concentration(s) of [Active Ingredient or Active Moiety] in Type C Medicated Feeds,'' followed by the approved concentration(s) of each active ingredient in Type C medicated feed(s) to be manufactured from the Type A medicated article for the approved or conditionally approved indications for use (see proposed § 201.409(a)(9)(i)). If an active ingredient is a salt or other noncovalent derivative, its concentration in the Type A medicated article in the ''Active Ingredient'' or ''Active Ingredients'' section (see proposed § 201.409(a)(7)) may be expressed on the basis of the full active ingredient (*i.e.,* including the salt or other noncovalent derivative) or the active moiety. If an active ingredient is a salt or other noncovalent derivative and its concentration in the Type A medicated article was expressed in the ''Active Ingredient'' or Active Ingredients'' section based on the active moiety, the proposed rule would require the approved concentration(s) in the Type C medicated feeds to also be expressed based on the active moiety, and the title of this subsection would be required to include the name of the active moiety instead of the active ingredient (see proposed § 201.409(a)(9)(i)). Consistent expression of the concentrations of active ingredients on the Type A medicated article label may reduce the risk of mixing errors when manufacturing medicated feeds from the Type A medicated article.

Multiple Type C medicated feeds may be approved or conditionally approved for a Type A medicated article. Also, different concentrations, or ranges of concentrations, of the active ingredient may be approved or conditionally approved for different indications for use. This subsection of the Type A medicated article label would clarify this information for manufacturers of medicated feeds manufactured from the Type A medicated article.

ii. ''*Mixing Directions.*'' The proposed rule would require this subsection of the ''Directions'' section of the Type A medicated article label to have the heading ''Mixing Directions,'' followed by the approved mixing directions for the manufacture of approved medicated feeds from the Type A medicated article for each approved or conditionally approved indication for use (see proposed § 201.409(a)(9)(ii)). An intermediate mixing step (called preblend step) is sometimes required to manufacture medicated feeds from the Type A medicated article. For example, the Type A medicated article may need to be preblended with a small amount of one or more feed ingredients before being added to the rest of the feed ingredients to increase the uniformity of the drug distribution in the finished medicated feed. The directions for such a preblend step would also be required to be included in this subsection of the Type A medicated article label.

iii. ''*Feeding Directions.*'' The proposed rule would require the last subsection in the ''Directions'' section of the Type A medicated article label to have the heading ''Feeding Directions,'' followed by the approved feeding directions for each approved or conditionally approved indication for use for Type C medicated feeds approved or conditionally approved to be manufactured from the Type A medicated article (see proposed § 201.409(a)(9)(iii)).

j. ''*Warnings.*'' The proposed rule would require this section of the Type A medicated article label for all approved or conditionally approved Type A medicated articles, and it would have the heading ''Warnings,'' followed by all warnings (see proposed § 201.409(a)(10)). This section of the Type A medicated article label would have the same subsections as described in § 201.405(a)(10) in full prescribing information for Rx new animal drugs, except that the ''Animal Safety Warnings'' subsection would be the same as described in proposed § 201.407(a)(7)(iii) for full product information for OTC new animal drugs.

k. ''*Additional Recommendations.*'' For new animal drugs having precautions, the proposed rule would require this section of the Type A medicated article label to have the heading ''Additional Recommendations,'' followed by all precautions (see proposed § 201.409(a)(11)). This section of the Type A medicated article label would be

the same as described in proposed § 201.407(a)(8) for full product information for OTC new animal drugs. For VFD new animal drugs, this section would include precautions directed to veterinarians as well as the layperson.

l. ''*Other Effects You May Notice.*'' For new animal drugs that have effects on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences, and FDA determines that these effects are required to be described on labeling, the proposed rule would require this section of the Type A medicated article label to have the heading ''Other Effects You May Notice,'' followed by a description of the effects (see proposed § 201.409(a)(12)). This section of the Type A medicated article label would be the same as described in proposed § 201.407(a)(9) for full product information for OTC new animal drugs.

m. ''*Net Weight.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Net Weight,'' followed by the net weight of the Type A medicated article in the immediate container (see proposed § 201.409(a)(13)).

n. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Storage, Handling, and Disposal,'' followed by storage information for the Type A medicated article, as well as any required handling and disposal information (see proposed § 201.409(a)(14)). This section of the Type A medicated article label would be the same as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs.

o. ''*Questions/Comments?*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Questions/Comments?,'' followed by the sponsor's contact information for feed manufacturers or other users of the Type A medicated article to facilitate requesting additional information or to report suspected adverse drug experiences. FDA's contact information for voluntary reporting of adverse drug experiences for animal drugs would also be required (see proposed § 201.409(a)(15)). The ''Questions/Comments?'' section of the Type A medicated article label would be similar to the ''Questions/Comments?'' section in proposed § 201.407(a)(14) for full product information for OTC new animal drugs.

The sponsor's contact information would be the name of the manufacturer, packer, or distributor, whichever is identified in the ''Name and place of business'' section of the Type A medicated article label (see proposed § 201.409(a)(17)). If more than one business is identified in the ''Name and place of business'' section of the Type A medicated article label, the drug sponsor would select the most appropriate of these businesses to use in the ''Questions/Comments?'' section to provide additional information about the Type A medicated article and to contact regarding suspected adverse drug experiences.

The statements in this section of the Type A medicated article label would be required to be structured as follows: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report side effects, contact [insert name of business] at [insert business telephone number]. For additional information about reporting side effects for animal drugs, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Sponsors can search FDA's website or contact FDA by telephone to find the current FDA telephone number or web address for voluntary reporting of adverse drug experiences for animal drug.

p. NADA/ANADA approval statement. For approved or generic approved Type A medicated articles, the proposed rule would require this section of the Type A medicated article label to include an ''NADA approval statement'' or ''ANADA approval statement,'' respectively (see proposed § 201.409(a)(16)). This section of the Type A medicated article label would be the same as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs.

q. Name and place of business. The proposed rule would require this section of the Type A medicated article label to identify the name and place of business of the manufacturer, packer, or distributor (see proposed § 201.409(a)(17)). This section of the Type A medicated article label would be the same as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs.

r. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number of the Type A medicated article within the immediate container. A lot or control number would help us to more easily identify and trace back a specific lot of a Type A medicated article should a problem be reported to FDA (see proposed § 201.409(a)(18)). In accordance with § 226.58(d) of this chapter, the proposed rule would also require this section of the Type A medicated article label to include the expiration date of the Type A medicated article within the immediate container. An expiration date is important to ensure the safe and effective use of products.

Alternatively, the proposed rule would allow for this section of the Type A medicated article label to refer to the location on the Type A medicated article label or immediate container where the lot or control number and expiration date are printed (see proposed § 201.409(a)(18)). As an example, if the lot number and expiration date are printed on the bottom half of the back of the bag containing the Type A medicated article, then the Type A medicated article label may state in this section, ''See bottom back half of bag for lot number and expiration date.''

s. ''*Revision Date.*'' The proposed rule would require this section of the Type A medicated article label to have the heading ''Revision Date,'' followed by the date of the most recent revision of the Type A medicated article label, listing the month followed by the year (see proposed § 201.409(a)(19)). This information is important to ensure that the most current approved version of the Type A medicated article label is being used.

2. Representative Type B Medicated Feed Labeling (Proposed § 201.409(b))

The proposed rule would establish content and format requirements for representative Type B medicated feed labeling for new animal drugs approved or conditionally approved for use in animal feeds (see proposed § 201.409(b)). A Type B medicated feed is intended solely for the manufacture of other medicated feeds (Type B or Type C). It serves as an intermediate medicated feed not approved for feeding to the target animals. It is manufactured by diluting a Type A medicated article or another Type B medicated feed with non-medicated feed, and at least 25 percent of its weight is from nutritional ingredients (see § 558.3(b)(3)). Representative Type B medicated feed labeling is template labeling approved by FDA as part of an NADA or CNADA for a Type A medicated article.

Representative Type B medicated feed labeling approved in the NADA or CNADA provide feed mills the minimal information that must be included on

the final printed labels prepared for the Type B medicated feeds manufactured containing the Type A medicated article to provide for safe and effective use of the new animal drug for its approved or conditionally approved indication(s) for use.

The proposed rule would require the following information to be presented on the representative Type B medicated feed labeling for an approved or conditionally approved new animal drug and in the following order (see proposed § 201.409(b)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs, proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs, or proposed § 201.409(a) for the Type A medicated article label.

a. Description of the Type B medicated feed. The proposed rule would require this section of the representative Type B medicated feed labeling to provide a description of the Type B medicated feed (see proposed § 201.409(b)(1)). This section of the representative Type B medicated feed labeling would serve as a placeholder for the proprietary name of the final Type B medicated feed to be added by the feed manufacturer to the label of the final Type B medicated feed manufactured in accordance with the approved representative Type B labeling.

Representative Type B medicated labeling may be approved or conditionally approved for multiple Type B medicated feeds within an application. The proposed rule would require the description of each approved Type B medicated feed to distinguish it from any other Type B medicated feeds approved or conditionally approved within the same application (see proposed § 201.409(b)(1)(i)). Distinguishing information may include the animals and/or indications for use for which Type C medicated feeds manufactured from the Type B medicated feed are approved or conditionally approved and/or other characteristics of the Type B medicated feeds.

The proposed rule would require that the description of the approved Type B medicated feed not include the proprietary name of a Type A medicated article (see proposed § 201.409(b)(1)(ii)). The proprietary name of a Type A medicated article is specific to the Type A medicated article; use of that proprietary name in the description of a Type B medicated feed may incorrectly imply that the Type B medicated feed is a Type A medicated article.

b. Established name of the Type B medicated feed. The proposed rule would require this section of the representative Type B medicated feed labeling to include the established name of the Type B medicated feed. The established name of the Type B medicated feed would include the active moiety or active ingredient of each new animal drug, as determined by FDA, followed by an identifying statement of either ''Type B medicated feed'' or ''Type B liquid medicated feed,'' as applicable (see proposed § 201.409(b)(2)). The identifying statements also clearly designate the medicated feeds as Type B (as opposed to a Type C) medicated feeds. The identifying statements also distinguish Type B liquid medicated feeds from other Type B medicated feeds, which is important because Type B liquid medicated feeds have unique approval and labeling requirements (see § 558.5 (21 CFR 558.5)).

c. VFD cautionary statement. For VFD new animal drugs, the proposed rule would require this section of the representative Type B medicated feed labeling to provide the VFD cautionary statement, in accordance with § 558.6(a)(6), as described in proposed § 201.409(a)(2) for the Type A medicated article label (see proposed § 201.409(b)(3)).

d. ''*Do Not Feed Undiluted.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to state, ''Do Not Feed Undiluted'' (see proposed § 201.409(b)(4)). This statement would remind users that the Type B medicated feed is not to be fed directly to animals.

e. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the representative Type B medicated feed labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.409(b)(5)).

f. ''*Indications for Use.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Indications for Use,'' followed by the approved or conditionally approved indications(s) and target animal(s), as described in proposed § 201.407(a)(3) for full product information for OTC new animal drugs, with the exception of the heading. In addition, this section of the representative Type B medicated feed labeling would include only the indications for use applicable to the specific Type B medicated feed to which the representative labeling applies (see proposed § 201.409(b)(6)).

g. Extralabel use statement. The proposed rule would require this section of the representative Type B medicated feed labeling to include an extralabel use statement, as described in proposed § 201.409(a)(6) for the Type A medicated article label (see proposed § 201.409(b)(7)).

h. ''*Active Ingredient*'' *or* ''*Active Ingredients.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and approved concentration(s) of each active ingredient (see proposed § 201.409(b)(8)). If the Type B medicated feed contains one active ingredient, the proposed rule would require this section of the representative Type B medicated feed labeling to be titled ''Active Ingredient.'' If the Type B medicated feed contains more than one active ingredient, the proposed rule would require this section of the representative Type B medicated feed labeling to be titled ''Active Ingredients.'' FDA approves a single concentration or a range of concentrations of each active ingredient for Type B medicated feeds and their representative Type B medicated feed labeling. However, the final Type B medicated feed label would only include a single concentration of each active ingredient. If a range of concentrations of the active ingredient(s) is approved or conditionally approved for Type B medicated feeds, the representative Type B medicated feed labeling would be required to include a footnote, placed at the bottom of the page of the representative Type B medicated feed labeling containing the ''Active Ingredient'' or ''Active Ingredients'' section, which instructs feed manufacturers that the final printed Type B medicated feed label must only include a single concentration for each active ingredient.

i. ''*Guaranteed Analysis.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Guaranteed Analysis,'' followed by the nutritional content guarantees of the Type B medicated feed appropriate for the approved target animals in addition to any other required specifications (see proposed § 201.409(b)(9)). The Type B medicated feed will be used to make a Type C medicated feed that will be included as part of the target animals' diet or serve

as their complete diet. Therefore, the feed manufacturer and user must be aware of the nutritional content of the Type B medicated feed to properly balance the nutritional content of the diet of the target animal. Without this nutritional content information being made available to the manufacturer and user of the medicated feed, the animals' diet may be imbalanced, *e.g.,* either under- or over-feeding critical nutrients, which could be harmful to the health of the target animals. For this reason, information of this type may be considered material under section 201(n) of the FD&C Act such that it would be required to be disclosed on the representative Type B feed labeling.

Additional specifications may also be required in this section of the representative Type B medicated feed labeling, such as the range of pH and/or range of percent dry matter. For example, the pH and/or ratio of dry matter to moisture (expressed as percent dry matter) of a liquid medicated feed may affect the stability of the new animal drug(s) it contains, such that a specific Type B liquid medicated feed would be approved only within a specific range of pH and/or percent dry matter (see § 558.5(d)(1) and (2)).

j. ''*Ingredients.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Ingredients,'' followed by information relative to feed ingredients (see proposed § 201.409(b)(10)). This information would include a statement that the feed ingredients must be listed on each final printed Type B medicated feed label by their common or usual names in descending order of predominance by weight, in accordance with § 501.4(a) (21 CFR 501.4(a)), including their collective names where permitted, in accordance with § 501.4(b)(13). Also included would be a statement that spices, flavorings, colorings, and chemical preservatives, if used, must be declared on each final printed Type B medicated feed label, in accordance with § 501.22 (21 CFR 501.22).

k. ''*Mixing Directions.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Mixing Directions,'' followed by approved mixing directions for the manufacture of a Type C medicated feed(s) or another Type B medicated feed(s), as applicable, from the Type B medicated feed for which the representative Type B medicated feed labeling applies (see proposed § 201.409(b)(11)).

l. ''*Warnings.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Warnings,'' followed by the ''Warnings'' section, as described in proposed § 201.409(a)(10) for the Type A medicated article label. In addition, this section of the representative Type B medicated feed labeling would include only the warnings applicable to the specific Type B medicated feed to which the representative labeling applies (see proposed § 201.409(b)(12)).

m. ''*Additional Recommendations.*'' For new animal drugs having precautions, the proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Additional Recommendations,'' followed by the precautions, as described in proposed § 201.407(a)(8) for full product information for OTC new animal drugs. In addition, this section of the representative Type B medicated feed labeling would include only the precautions applicable to the specific Type B medicated feed to which the representative labeling applies (see proposed § 201.409(b)(13)).

n. ''*Other Effects You May Notice.*'' For new animal drugs that have effects on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences, and FDA determines that these effects are required to be described on labeling, the proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Other Effects You May Notice,'' followed by a description of the effects. This section of the representative Type B medicated feed labeling would be the same as described in proposed § 201.407(a)(9) for full product information for OTC new animal drugs. In addition, this section of the representative Type B medicated feed labeling would include only statements of other effects applicable to the specific Type B medicated feed to which the representative Type B medicated feed labeling applies (see proposed § 201.409(b)(14)).

o. Name and place of business. The proposed rule would require this section of the representative Type B medicated feed labeling to provide for identification of the name and place of business of the manufacturer, packer, or distributor of the final Type B medicated feed on the final printed Type B medicated feed label, in accordance with § 501.5 (see proposed § 201.409(b)(15)).

p. ''*Net Weight.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Net Weight,'' followed by space to provide for a statement on the final printed Type B medicated feed label of the net weight of the Type B medicated feed in the immediate container (see proposed § 201.409(b)(16)).

q. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Storage, Handling, and Disposal,'' followed by storage information for the Type B medicated feed, as well as any required handling and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs (see proposed § 201.409(b)(17)).

r. ''*Questions/Comments?*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Questions/Comments?,'' followed by statements providing contact information for use by feed manufacturers or other users of the final Type B medicated feed to request additional information on the product and/or to report problems with the medicated feed (see proposed § 201.409(b)(18)). The first statement would provide placeholders for the name and contact information of the business of the manufacturer, packer, or distributor of the final Type B medicated feed to later be inserted by the business. The second statement would provide FDA contact information for reporting adverse drug experiences for animal drugs and would be required to be inserted by the sponsor of the new animal drug application.

s. ''*Lot, Batch, or Control Number.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Lot, Batch, or Control Number,'' followed by space to provide for an identifying lot, batch, or control number on the final printed Type B medicated feed label (see proposed § 201.409(b)(19)).

t. ''*Expiration Date.*'' For Type B medicated feeds requiring an expiration date, in accordance with § 514.1(b)(5)(x), the proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Expiration Date,'' followed by space to provide for the expiration date to be printed on the final printed Type B medicated feed label. In addition, the approved expiration period would need to be included in this section of the representative Type B medicated feed labeling (see proposed § 201.409(b)(20)).

u. ''*Revision Date.*'' The proposed rule would require this section of the representative Type B medicated feed labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the representative Type B medicated feed labeling, listing the month followed by the year (see proposed § 201.409(b)(21)). This information is important to ensure that the most current approved version of the representative Type B medicated feed labeling is being used.

3. Representative Type C Medicated Feed Labeling (Proposed § 201.409(c))

The proposed rule would establish content and format requirements for representative Type C medicated feed labeling for new animal drugs approved or conditionally approved for use in animal feeds (see proposed § 201.409(c)). Type C medicated feed is fed directly to target animals. It may also be used in the manufacture of another Type C medicated feed. When fed directly to target animals, it is intended to be the animals' complete feed or part of their total diet. It is manufactured by diluting a Type A medicated article, a Type B medicated feed, or another Type C medicated feed with non-medicated feed, and it contains a substantial quantity of nutritional ingredients (see § 558.3(b)(4)).

Representative Type C medicated feed labeling approved in the NADA or CNADA provide feed mills the minimal information that must be included on the final printed labels prepared for the Type C medicated feeds manufactured containing the Type A medicated article to provide for safe and effective use of the new animal drug for its approved or conditionally approved indication(s) for use.

The proposed rule would require the following information to be presented on the representative Type C medicated feed labeling for an approved or conditionally approved new animal drug and in the following order (see proposed § 201.409(c)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs, proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs, proposed § 201.409(a) for the Type A medicated article label, or proposed § 201.409(b) for representative Type B medicated feed labeling.

a. Description of the Type C medicated feed. The proposed rule would require this section of the representative Type C medicated feed labeling to provide a description of the Type C medicated feed (see proposed § 201.409(c)(1)). This section of the representative Type C medicated feed labeling would serve as a placeholder for the proprietary name of the final Type C medicated feed to be added by the feed manufacturer to the label of the final Type C medicated feed manufactured in accordance with the approved representative Type C labeling.

Representative Type C medicated labeling may be approved or conditionally approved for multiple Type C medicated feeds within an application. The proposed rule would require the description of each approved Type C medicated feed to distinguish it from any other Type C medicated feeds approved or conditionally approved within the same application (see proposed § 201.409(c)(1)(i)). Distinguishing information may include the animals and/or indications for use for which Type C medicated feeds are approved or conditionally approved and/or other characteristics of the Type C medicated feeds.

The proposed rule would require that the description of the approved Type C medicated feed not include the proprietary name of a Type A medicated article (see proposed § 201.409(c)(1)(ii)). The proprietary name of a Type A medicated article is specific to the Type A medicated article; use of that proprietary name in the description of a Type C medicated feed may incorrectly imply that the Type C medicated feed is a Type A medicated article.

b. Established name of the Type C medicated feed. The proposed rule would require this section of the representative Type C medicated feed labeling to include the established name of the Type C medicated. The established name of the Type C medicated feed would include the active moiety or active ingredient of each new animal drug, as determined by FDA, followed by an identifying statement of, ''Type C medicated feed,'' ''Type C liquid medicated feed,'' ''Type C top-dress medicated feed,'' ''Type C free-choice medicated feed,'' or ''Type C liquid free-choice medicated feed,'' as applicable (see proposed § 201.409(c)(2)). The identifying statements also clearly designate the medicated feeds as Type C (as opposed to a Type B) medicated feeds. The identifying statements also distinguish Type C liquid medicated feeds from other Type C medicated feeds, which is important because Type C liquid medicated feeds have unique approval and labeling requirements (see § 558.5). Similarly, Type C free-choice medicated feeds have specific requirements for their approval (see § 510.455 (21 CFR 510.455)).

c. VFD cautionary statement. For VFD new animal drugs, the proposed rule would require this section of the representative Type C medicated feed labeling to provide the VFD cautionary statement, in accordance with § 558.6(a)(6), as described in proposed § 201.409(a)(2) for the Type A medicated article label (see proposed § 201.409(c)(3)).

d. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the representative Type C medicated feed labeling to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.409(c)(4)).

e. ''*Indications for Use.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Indications for Use,'' followed by the approved or conditionally approved indications(s) and target animal(s), as described in proposed § 201.407(a)(3) for full product information for OTC new animal drugs, with the exception of the heading. In addition, this section of the representative Type C medicated feed labeling would include only the indications for use applicable to the specific Type C medicated feed to which the representative labeling applies (see proposed § 201.409(c)(5)).

f. Extralabel use statement. The proposed rule would require this section of the representative Type C medicated feed labeling to include an extralabel use statement, as described in proposed § 201.409(a)(6) for the Type A medicated article label (see proposed § 201.409(c)(6)).

g. ''*Active Ingredient*'' *or* ''*Active Ingredients.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and approved concentration(s) of each active ingredient (see proposed § 201.409(c)(7)). If the Type C medicated feed contains one active ingredient, the proposed rule would require this section of the representative Type C medicated feed labeling to be entitled ''Active Ingredient.'' If the Type C medicated feed contains more than one active ingredient, the proposed rule would require this section of the representative Type C medicated feed

labeling to be entitled ''Active Ingredients.'' We approve a single concentration or a range of concentrations of each active ingredient for Type C medicated feeds and their representative Type C medicated feed labeling. However, the final Type C medicated feed label would only include a single concentration of each active ingredient. If a range of concentrations of the active ingredient(s) is approved or conditionally approved for Type C medicated feeds, the representative Type C medicated feed labeling would be required to include a footnote, placed at the bottom of the page of the representative Type C medicated feed labeling containing the ''Active Ingredient'' or ''Active Ingredients'' section, which instructs feed manufacturers that the final printed Type C medicated feed label must include only a single concentration for each active ingredient.

h. ''*Guaranteed Analysis.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Guaranteed Analysis,'' followed by the nutritional content guarantees of the Type C medicated feed and any other required specifications, as described in proposed § 201.409(b)(9) for representative Type B medicated feed labeling (see proposed § 201.409(c)(8)).

i. ''*Ingredients.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Ingredients,'' followed by information relative to feed ingredients (see proposed § 201.409(c)(9)).

For Type C medicated feeds that are not Type C free-choice medicated feeds, proposed § 201.409(b)(9)(i) would require the heading to be followed by a statement that the feed ingredients must be listed on each final printed Type C medicated feed label by their common or usual names in descending order of predominance by weight, in accordance with § 501.4(a), including their collective names where permitted, in accordance with § 501.4(b)(13). Also included would be a statement that spices, flavorings, colorings, and chemical preservatives, if used, must be declared on the final printed Type C medicated feed label, in accordance with § 501.22.

For Type C free-choice medicated feeds, the proposed rule would require the heading to be followed by a listing of the feed ingredients and their inclusion rates, including the drug concentrations exactly as they appear in the approved non-proprietary formula published for the specific new animal drug in part 558 (see proposed § 201.409(b)(9)(ii)).

j. ''*Feeding Directions.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Feeding Directions,'' followed by the approved feeding directions (see proposed § 201.409(c)(10)). This section of representative Type C medicated feed labeling would include only the feeding directions applicable to the specific Type C medicated feed to which the representative Type C medicated feed labeling applies.

k. ''*Warnings.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Warnings,'' followed by the ''Warnings'' section, as described in proposed § 201.409(a)(10) for the Type A medicated article label. In addition, this section of the representative Type C medicated feed labeling would include only the warnings applicable to the specific Type C medicated feed to which the representative labeling applies (see proposed § 201.409(c)(11)).

l. ''*Additional Recommendations.*'' For new animal drugs having precautions, the proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Additional Recommendations,'' followed by the precautions, as described in proposed § 201.407(a)(8) for full product information for OTC new animal drugs. In addition, this section of the representative Type C medicated feed labeling would include only the precautions applicable to the specific Type C medicated feed to which the representative labeling applies (see proposed § 201.409(c)(12)).

m. ''*Other Effects You May Notice.*'' For new animal drugs that have effects on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences, and FDA determines that these effects are required to be described on labeling, the proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Other Effects You May Notice,'' followed by a description of the effects. This section of the representative Type C medicated feed labeling would be the same as described in proposed § 201.407(a)(9) for full product information for OTC new animal drugs. In addition, this section of the representative Type C medicated feed labeling would include only statements of other effects applicable to the specific Type C medicated feed to which the representative Type C labeling applies (see proposed § 201.409(c)(13)).

n. Name and place of business. The proposed rule would require this section of the representative Type C medicated feed labeling to provide for identification of the name and place of business of the manufacturer, packer, or distributor of the final Type C medicated feed on the final printed Type C medicated feed label, in accordance with § 501.5 (see proposed § 201.409(c)(14)).

o. ''*Net Weight.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Net Weight,'' followed by space to provide for a statement on the final printed Type C medicated feed label of the net weight of the Type C medicated feed in the immediate container (see proposed § 201.409(c)(15)).

p. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Storage, Handling, and Disposal,'' followed by storage information for the Type C medicated feed, as well as any required, handling and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs (see proposed § 201.409(c)(16)).

q. ''*Questions/Comments?*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Questions/Comments?,'' followed by statements providing contact information for use by feed manufacturers or other users of the final Type C medicated feed to request additional information on the product and/or to report problems with the medicated feed (see proposed § 201.409(c)(17)). The first statement would provide placeholders for the name and contact information of the business of the manufacturer, packer, or distributor of the final Type C medicated feed to later be inserted by the business. The second statement would provide FDA contact information for reporting adverse drug experiences for animal drugs and would be required to be inserted by the sponsor of the new animal drug application.

r. ''*Lot, Batch, or Control Number.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Lot, Batch, or Control Number,'' followed by space to provide for an identifying lot, batch, or control

number on the final printed Type C medicated feed label (see proposed § 201.409(c)(19)).

s. ''*Expiration Date.*'' For Type C medicated feeds requiring an expiration date, in accordance with § 514.1(b)(5)(x), the proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Expiration Date,'' followed by space to provide for the expiration date to be printed on the final printed Type C medicated feed label. In addition, the approved expiration period would need to be included in this section of the representative Type C medicated feed labeling (see proposed § 201.409(c)(19)).

t. ''*Revision Date.*'' The proposed rule would require this section of the representative Type C medicated feed labeling to have the heading ''Revision Date,'' followed by the date of the most recent revision of the representative Type C medicated feed labeling, listing the month followed by the year (see proposed § 201.409(c)(20)). This information is important to ensure that the most current approved version of the representative Type C medicated feed labeling is being used.

4. Proprietary Type B Medicated Feed Label (Proposed § 201.409(d))

The proposed rule would establish content and format requirements for a proprietary Type B medicated feed label for new animal drugs approved or conditionally approved for use in animal feeds (see proposed § 201.409(d)). A proprietary Type B medicated feed is intended solely for the manufacture of Type C medicated feeds or other Type B medicated feeds and is not approved or conditionally approved for feeding to the target animals. For some proprietary Type B medicated feeds, the formulation and labeling are approved in an NADA. In other situations, the underlying data and labeling for the proprietary Type B medicated feed to support the approved uses are maintained in a VMF. For example, this would include situations in which a proprietary Type B medicated feed is manufactured via modification to an approved formulation published in the CFR or where a feed manufacturer creates its own proprietary formulation. The application for a proprietary Type B medicated feed will include the proprietary label for the final Type B medicated feed and representative Type C medicated feed labeling that directs the preparation of final printed labels for Type C medicated feeds manufactured from the proprietary Type B medicated feed. A proprietary Type B medicated feed label is on the immediate container, which is typically a bag or bulk container.

The proposed rule would require the following information to be presented on the proprietary Type B medicated feed label for an approved or conditionally approved new animal drug and in the following order (see proposed § 201.409(d)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs, proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs, or proposed § 201.409(a) for the Type A medicated article label.

a. Proprietary Type B medicated feed identification. The proposed rule would require this section of the proprietary Type B medicated feed label to identify the Type B medicated feed (see proposed § 201.409(d)(1)). This section of the proprietary Type B medicated feed label would be required to include the following components in order:

i. *Proprietary name of the Type B medicated feed.* The proposed rule require this subsection of the proprietary Type B medicated feed label to include the proprietary name of the Type B medicated feed (see proposed § 201.409(d)(1)(i)).

ii. *Established name of the Type B medicated feed.* The proposed rule would require this subsection of the proprietary Type B medicated feed label to include the established name of the Type B medicated feed. The established name of the Type B medicated feed would include the active moiety or active ingredient of each new animal drug, as determined by FDA, followed by an identifying statement of either ''*Type B medicated feed*'' or ''*Type B liquid medicated feed,*'' as applicable (see proposed § 201.409(d)(1)(ii)). The identifying statements also clearly designate the medicated feed as a Type B (as opposed to a Type C) medicated feed. The identifying statements also distinguish Type B liquid medicated feeds from other Type B medicated feeds, which is important because Type B liquid medicated feeds have unique approval and labeling requirements (see § 558.5).

b. VFD cautionary statement. For VFD new animal drugs, the proposed rule would require this section of the proprietary Type B medicated feed label to provide the VFD cautionary statement, in accordance with § 558.6(a)(6), as described in proposed § 201.409(a)(2) for the Type A medicated article label (see proposed § 201.409(d)(2)).

c. ''*Do Not Feed Undiluted.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to state, ''Do Not Feed Undiluted'' (see proposed § 201.409(d)(3)). This statement would remind users that the Type B medicated feed is not to be fed directly to animals.

d. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the proprietary Type B medicated feed label to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.409(d)(4)).

e. ''*Indications for Use.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Indications for Use,'' followed by the approved or conditionally approved indications(s) and target animal(s), as described in proposed § 201.407(a)(3) for full product information for OTC new animal drugs, with the exception of the heading (see proposed § 201.409(d)(5)).

f. Extralabel use statement. The proposed rule would require this section of the proprietary Type B medicated feed label to include an extralabel use statement, as described in proposed § 201.409(a)(6) for the Type A medicated article label (see proposed § 201.409(d)(6)).

g. ''*Active Ingredient*'' *or* ''*Active Ingredients.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and approved concentration of each active ingredient (see proposed § 201.409(d)(7)). If the proprietary Type B medicated feed contains one active ingredient, the proposed rule would require this section of the proprietary Type B medicated feed label to be entitled ''Active Ingredient.'' If the proprietary Type B medicated feed contains more than one active ingredient, the proposed rule would require this section of the proprietary Type B medicated feed label to be entitled ''Active Ingredients.'' Because the proprietary Type B medicated feed label applies to a final Type B medicated feed, a single concentration would be required for each active ingredient rather than a range.

h. ''*Guaranteed Analysis.*'' The proposed rule would require this section of the proprietary Type B

medicated feed label to have the heading ''Guaranteed Analysis,'' followed by the nutritional content guarantees and any other required specifications for the proprietary Type B medicated feed (see proposed § 201.409(d)(8)).

i. ''*Ingredients.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Ingredients,'' followed by a listing of the feed ingredients in the proprietary Type B medicated feed. The feed ingredients would be required to be listed by their common or usual names in descending order of predominance by weight, in accordance with § 501.4(a), including their collective names where permitted, in accordance with § 501.4(b)(13) (see proposed § 201.409(d)(9)(i)). Spices, flavorings, colorings, and chemical preservatives, if used, would be required to be declared, in accordance with § 501.22 (see proposed § 201.409(d)(9)(ii)).

j. ''*Mixing Directions.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Mixing Directions,'' followed by the approved mixing directions for the manufacture of a Type C medicated feed(s) or another Type B medicated feed(s), if applicable, from the proprietary Type B medicated feed (see proposed § 201.409(d)(10)).

k. ''*Warnings.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Warnings,'' followed by the ''Warnings'' section, as described in proposed § 201.409(a)(10) for the Type A medicated article label (see proposed § 201.409(d)(11)).

l. ''*Additional Recommendations.*'' For new animal drugs having precautions, the proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Additional Recommendations,'' followed by all precautions, as described in proposed § 201.407(a)(8) for full product information for OTC new animal drugs (see proposed § 201.409(d)(12)).

m. ''*Other Effects You May Notice.*'' For new animal drugs that have effects on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences, and FDA determines that these effects are required to be described on labeling, the proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Other Effects You May Notice,'' followed by a description of the effects. This section of the proprietary Type B medicated feed label would be the same as described in proposed § 201.407(a)(9) for full product information for OTC new animal drugs (see proposed § 201.409(d)(13)).

n. ''*Net Weight.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Net Weight,'' followed by the net weight of the Type B medicated feed in the immediate container (see proposed § 201.409(d)(14)).

o. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Storage, Handling, and Disposal,'' followed by storage information for the Type B medicated feed, as well as any required handling and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs (see proposed § 201.409(d)(15)).

p. ''*Questions/Comments?*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Questions/Comments?,'' followed by the sponsor's contact information for feed manufacturers or other users of the Type B medicated feed to facilitate requesting additional information on the product or to report suspected adverse drug experiences. FDA's contact information for voluntary reporting of adverse drug experiences for animal drugs would also be required (see proposed § 201.409(d)(16)).

The sponsor's contact information would be the name of the manufacturer, packer, or distributor, whichever is identified in the ''Name and place of business'' section of the Type B medicated feed (see proposed § 201.409(d)(18)). If more than one business is identified in the ''Name and place of business'' section of the proprietary Type B medicated feed label, the drug sponsor would select the most appropriate of these businesses to use in the ''Questions/Comments?'' section to provide additional information about the Type B medicated feed and to contact regarding suspected adverse drug experiences.

The statements in this section of the proprietary Type B medicated feed label would be required to be structured as follows: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report side effects, contact [insert name of business] at [insert business telephone number]. For additional information about reporting problems with medicated feeds, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Sponsors can search FDA's website or contact FDA by telephone to find the current FDA telephone number or web address for voluntary reporting of adverse drug experiences for animal drug.

q. NADA/ANADA approval statement. For approved or generic approved proprietary Type B medicated feeds, the proposed rule would require this section of the proprietary Type B medicated feed label to include an ''NADA approval statement'' or ''ANADA approval statement,'' respectively, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.409(d)(17)).

r. Name and place of business. The proposed rule would require this section of the proprietary Type B medicated feed label to identify name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs (see proposed § 201.409(d)(18)).

s. ''*Lot, Batch, or Control Number.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Lot, Batch, or Control Number,'' followed by the identifying lot, batch, or control number of the Type B medicated feed. Alternatively, the proposed rule would allow for this section of the proprietary Type B medicated feed label to refer to the location on the proprietary Type B medicated feed label or immediate container where the lot, batch, or control number is printed (see proposed § 201.409(d)(19)).

t. ''*Expiration Date.*'' For Type B medicated feeds requiring an expiration date, in accordance with § 514.1(b)(5)(x), the proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Expiration Date,'' followed by the expiration date of the proprietary Type B medicated feed. Alternatively, the proposed rule would allow for this section of the proprietary Type B medicated feed label to refer to the location on the proprietary Type B medicated feed label or immediate container where the expiration date is printed (see proposed § 201.409(d)(20)).

u. ''*Revision Date.*'' The proposed rule would require this section of the proprietary Type B medicated feed label to have the heading ''Revision Date,''

followed by the date of the most recent revision of the proprietary Type B medicated feed label, listing the month followed by the year (see proposed § 201.409(d)(21)). This information is important to ensure that the most current approved version of the proprietary Type B medicated feed label is being used.

5. Proprietary Type C Medicated Feed Label (Proposed § 201.409(e))

The proposed rule would establish content and format requirements for a proprietary Type C medicated feed label for new animal drugs approved or conditionally approved for use in animal feeds (see proposed § 201.409(e)). FDA may approve or conditionally approve applications for proprietary final formulations of Type C medicated feeds. For some proprietary Type C medicated feeds, the formulation and labeling are approved in an NADA. In other situations, the underlying data and labeling for the proprietary Type C medicated feed to support the approved uses are maintained in a VMF. For example, this would include situations in which a proprietary Type C medicated feed is manufactured via modification to an approved formulation published in the CFR or where a feed manufacturer creates its own proprietary formulation. The application for a proprietary Type C medicated feed will include the proprietary label for the final Type C medicated feed. A proprietary Type C medicated feed label is on the immediate container, which is typically a bag or bulk container.

The proposed rule would require the following information to be presented on the proprietary Type C medicated feed label for an approved or conditionally approved new animal drug and in the following order (see proposed § 201.409(e)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs, proposed § 201.407(a) for full product information for approved or conditionally approved OTC new animal drugs, proposed § 201.409(a) for the Type A medicated article label, or proposed § 201.409(d) for the proprietary Type B medicated feed label.

a. Proprietary Type C medicated feed identification. The proposed rule would require this section of the proprietary Type C medicated feed label to identify the Type C medicated feed (see proposed § 201.409(e)(1)). This section of the proprietary Type C medicated feed label would be required to include the following components in order:

i. *Proprietary name of the Type C medicated feed.* The proposed rule would require this subsection of the proprietary Type C medicated feed label to include the proprietary name of the Type C medicated feed (see proposed § 201.409(e)(1)(i)).

ii. *Established name of the Type C medicated feed.* The proposed rule would require this subsection of the proprietary Type C medicated feed label to include the established name of the Type C medicated feed. The established name of the proprietary Type C medicated feed would include the active moiety or active ingredient of each new animal drug, as determined by FDA, followed by an identifying statement of, ''Type C medicated feed,'' ''Type C liquid medicated feed,'' ''Type C top-dress medicated feed,'' ''Type C free-choice medicated feed,'' or ''Type C liquid free-choice medicated feed,'' as applicable (see proposed § 201.409(e)(1)(ii)). The identifying statements also clearly designate the medicated feeds as Type C (as opposed to a Type B) medicated feeds. The identifying statements also distinguish Type C liquid medicated feeds from other Type C medicated feeds, which is important because Type C liquid medicated feeds have unique approval and labeling requirements (see § 558.5). Similarly, Type C free-choice medicated feeds have specific requirements for their approval (see § 510.455).

b. VFD cautionary statement. For VFD new animal drugs, the proposed rule would require this section of the proprietary Type C medicated feed label to provide the VFD cautionary statement, in accordance with § 558.6(a)(6), as described in proposed § 201.409(a)(2) for the Type A medicated article label (see proposed § 201.409(e)(2)).

c. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the proprietary Type C medicated feed label to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.409(e)(3)).

d. ''*Indications for Use.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Indications for Use,'' followed by the approved or conditionally approved indications(s) and target animal(s), as described in proposed § 201.407(a)(3) for full product information for OTC new animal drugs, with the exception of the heading (see proposed § 201.409(e)(4)).

e. Extralabel use statement. The proposed rule would require this section of the proprietary Type C medicated feed label to include an extralabel use statement, as described in proposed § 201.409(a)(6) for the Type A medicated article label (see proposed § 201.409(e)(5)).

f. ''*Active Ingredient*'' or ''*Active Ingredients.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Active Ingredient,'' or ''Active Ingredients,'' followed by the established name and approved concentration of each active ingredient (see proposed § 201.409(e)(6)). If the proprietary Type C medicated feed contains one active ingredient, the proposed rule would require this section of the proprietary Type C medicated feed label to be entitled ''Active Ingredient.'' If the proprietary Type C medicated feed contains more than one active ingredient, the proposed rule would require this section of the proprietary Type C medicated feed label to be entitled ''Active Ingredients.'' Because the proprietary Type C medicated feed label applies to a final Type C medicated feed, a single concentration would be required for each active ingredient rather than a range.

g. ''*Guaranteed Analysis.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Guaranteed Analysis,'' followed by the nutritional content guarantees and other required specifications for the final proprietary Type C medicated feed, as described in § 201.409(d)(8) for the proprietary Type B medicated feed label (see proposed § 201.409(e)(7)).

h. ''*Ingredients.*'' The proposed rule would require this section of the proprietary Type C medicated label to have the heading ''Ingredients,'' followed by a listing of the feed ingredients in the proprietary Type C medicated feed, as described in § 201.409(d)(9) for the proprietary Type B medicated feed label (see proposed § 201.409(e)(8)).

i. ''*Feeding Directions.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Feeding Directions,'' followed by the approved feeding directions (see proposed § 201.409(e)(9)).

j. ''*Warnings.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Warnings,''

followed by the ''Warnings'' section, as described in proposed § 201.409(a)(10) for the Type A medicated article label (see proposed § 201.409(e)(10)).

k. ''*Additional Recommendations.*'' For new animal drugs having precautions, the proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Additional Recommendations,'' followed by all precautions, as described in proposed § 201.407(a)(8) for full product information for OTC new animal drugs (see proposed § 201.409(e)(11)).

l. ''*Other Effects You May Notice.*'' For new animal drugs that have effects on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences, and FDA determines that these effects are required to be described on labeling, the proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Other Effects You May Notice,'' followed by a description of the effects. This section of the proprietary Type C label would be the same as described in proposed § 201.407(a)(9) for full product information for OTC new animal drugs (see proposed § 201.409(e)(12)).

m. ''*Net Weight.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Net Weight,'' followed by the net weight of the Type C medicated feed in the immediate container (see proposed § 201.409(e)(13)).

n. ''*Storage, Handling, and Disposal.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Storage, Handling, and Disposal,'' followed by storage information for the Type C medicated feed, as well as any required handling, and disposal information, as described in proposed § 201.405(a)(20) for full prescribing information for Rx new animal drugs (see proposed § 201.409(e)(14)).

o. ''*Questions/Comments?*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Questions/Comments?,'' followed by the sponsor's contact information for users of the Type C medicated feed to facilitate requesting additional information on the product or to report suspected adverse drug experiences. FDA's contact information for voluntary reporting of adverse drug experiences for animal drugs would also be required (see proposed § 201.409(e)(15)).

The sponsor's contact information would be the name of the manufacturer, packer, or distributor, whichever is identified in the ''Name and place of business'' section of the Type C medicated feed (see proposed § 201.409(e)(17)). If more than one business is identified in the ''Name and place of business'' section of the proprietary Type C medicated feed label, the drug sponsor would select the most appropriate of these businesses to use in the ''Questions/Comments?'' section to provide additional information about the Type C medicated feed and to contact regarding suspected adverse drug experiences.

The statements in this section of the proprietary Type C medicated feed label would be required to be structured as follows: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report side effects, contact [insert name of business] at [insert business telephone number]. For additional information about reporting side effects or other problems with medicated feeds, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Sponsors can search FDA's website or contact FDA by telephone to find the current FDA telephone number or web address for voluntary reporting of adverse drug experiences for animal drugs.

p. NADA/ANADA approval statement. For approved or generic approved proprietary Type C medicated feeds, the proposed rule would require this section of the proprietary Type C medicated feed label to include an ''NADA approval statement'' or ''ANADA approval statement,'' respectively, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.409(e)(16)).

q. Name and place of business. The proposed rule would require this section of the proprietary Type C medicated feed label to identify name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs (see proposed § 201.409(e)(17)).

r. ''*Lot, Batch, or Control Number.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Lot, Batch, or Control Number,'' followed by the identifying lot, batch, or control number of the Type C medicated feed. Alternatively, the proposed rule would allow for this section of the proprietary Type C medicated feed label to refer to the location on the proprietary Type C medicated feed label or immediate container where the lot, batch, or control number is printed (see proposed § 201.409(e)(18)).

s. ''*Expiration Date.*'' For Type C medicated feeds requiring an expiration date, in accordance with § 514.1(b)(5)(x), the proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Expiration Date,'' followed by the expiration date of the proprietary Type C medicated feed. Alternatively, the proposed rule would allow for this section of the proprietary Type C medicated feed label to refer to the location on the proprietary Type C medicated feed label or immediate container where the expiration date is printed (see proposed § 201.409(e)(19)).

t. ''*Revision Date.*'' The proposed rule would require this section of the proprietary Type C medicated feed label to have the heading ''Revision Date,'' followed by the date of the most recent revision of the proprietary Type C medicated feed label, listing the month followed by the year (see proposed § 201.409(e)(20)).

6. Other Approved Labeling for Type A Medicated Articles (Proposed § 201.409(f))

The proposed rule would establish content and format requirements for the information presented on other approved labeling for Type A medicated articles approved or conditionally approved for use in animal feeds. Other approved labeling for Type A medicated articles includes, but is not limited to, labeling on shipping cartons containing bags of Type A medicated articles (see proposed § 201.409(f)).

The proposed rule would require the following information to be presented on other approved labeling for Type A medicated articles and in the following order (see proposed § 201.409(f)). Unless otherwise indicated, this information would be the same as that required by proposed § 201.405(a) for full prescribing information for approved or conditionally approved Rx new animal drugs, or proposed § 201.409(a) for a Type A medicated article label.

a. Type A medicated article identification. The proposed rule would require this section of the other approved labeling for Type A medicated articles to include, in order, the proprietary name and the established

name of the Type A medicated article (see proposed § 201.409(f)(1)).

b. VFD cautionary statement. For VFD new animal drugs, the proposed rule would require this section of the other approved labeling for Type A medicated articles to provide the VFD cautionary statement, in accordance with § 558.6(a)(6), as described in proposed § 201.409(a)(2) for the Type A medicated article label (see proposed § 201.409(f)(2)).

c. ''*Active Ingredient*'' or ''*Active Ingredients.*'' The proposed rule would require this section of the other approved labeling for Type A medicated articles to have the heading ''Active Ingredient'' or ''Active Ingredients,'' followed by the established name and concentration of each active ingredient in the Type A medicated article. If the Type A medicated article contains one active ingredient, the proposed rule would require this section of the other approved labeling for Type A medicated articles to be entitled ''Active Ingredient.'' If the Type A medicated article contains more than one active ingredient, the proposed rule would require this section of the other approved labeling for Type A medicated articles to be entitled ''Active Ingredients'' (see proposed § 201.409(f)(3)).

d. Conditional approval statement. For conditionally approved new animal drugs, the proposed rule would require this section of the other approved labeling for Type A medicated articles to include a conditional approval statement, as described in proposed § 201.405(a)(3) for full prescribing information for Rx new animal drugs (see proposed § 201.409(f)(4)).

e. ''*Net Contents.*'' The proposed rule would require this section of the other approved labeling for Type A medicated articles to have the heading ''Net Contents,'' followed by the contents of the container to which the other approved labeling for Type A medicated articles applies (see proposed § 201.409(f)(5)).

f. ''*Storage and Handling.*'' The proposed rule would require this section of the other approved labeling for Type A medicated articles to have the heading ''Storage and Handling,'' followed by storage information for the Type A medicated article (see proposed § 201.409(f)(6)). Also, any handling information required for safe and effective use of the Type A medicated article would be included in this section. Information on disposal of the Type A medicated article would not be required to be included on other approved labeling for Type A medicated articles.

g. NADA/ANADA approval statement. For approved or generic approved proprietary Type A medicated articles, the proposed rule would require this section of the other approved labeling for Type A medicated articles to include an ''NADA approval statement'' or ''ANADA approval statement,'' respectively, as described in proposed § 201.405(a)(21) for full prescribing information for Rx new animal drugs (see proposed § 201.409(f)(7)).

h. Name and place of business. The proposed rule would require this section of the other approved labeling for Type A medicated articles to identify name and place of business of the manufacturer, packer, or distributor, as described in proposed § 201.405(a)(22) for full prescribing information for Rx new animal drugs (see proposed § 201.409(f)(8)).

i. ''*Lot Number and Expiration Date.*'' The proposed rule would require this section of the other approved labeling for Type A medicated articles to have the heading ''Lot Number and Expiration Date,'' followed by the identifying lot or control number(s) and the expiration date(s) of the Type A medicated article within the container (see proposed § 201.409(f)(9)). The container may include more than one lot of the Type A medicated article, and therefore, more than one lot or control number and expiration date may be listed in this section of other approved labeling for Type A medicated articles.

j. ''*Revision Date.*'' The proposed rule would require this section of the other approved labeling for Type A medicated articles to have the heading ''Revision Date,'' followed by the date of the most recent revision of the other approved labeling for Type A medicated articles, listing the month followed by the year (see proposed § 201.409(f)(10)).

G. Exemptions From Labeling Requirements for Approved or Conditionally Approved New Animal Drugs (Proposed § 201.411)

FDA would provide sponsors the opportunity to request an exemption from one or more specific requirements set forth in this proposed subpart on the basis that the requirements are not appropriate for the specific approved or conditionally approved new animal drug (see proposed § 201.411).

An exemption request would be required to be submitted to the corresponding application or investigational new animal drug file (INAD) for the new animal drug. A separate request would be required to be submitted for each new animal drug for which an exemption is sought. Requests for exemptions would be granted or denied by the Director of FDA's Center for Veterinary Medicine or the Director's designee (see proposed § 201.411(a)). The sponsor seeking an exemption would be required to: (1) describe why the particular requirement for which the exemption is requested was not appropriate for the new animal drug; (2) describe why granting the exemption would not adversely impact the safety or effectiveness of the use of the new animal drugs; and (3) include copies of all draft labeling proposed to be used for the new animal drug (see proposed § 201.411(b)). We anticipate that such exemptions would be rare.

H. Labeling Requirements for Certain Approved or Conditionally Approved New Animal Drugs (Proposed § 201.413)

This section of the proposed regulations would consolidate, and where appropriate, update existing labeling requirements pertaining to certain approved or conditionally approved new animal drugs that would continue to apply in addition to the other labeling requirements in proposed subpart H. Currently, the labeling requirements for these new animal drugs are dispersed throughout the regulations. It would be helpful to new animal drug sponsors and FDA reviewers if the proposed rule were to consolidate, and where appropriate, update the additional labeling requirements for these specific new animal drugs in the same subpart of the CFR as general labeling requirements for approved or conditionally approved new animal drugs.

This section also proposes a new labeling provision for all new animal drugs approved or conditionally approved for use in horses and anthelmintic new animal drugs for certain species of animals.

We may propose to amend § 201.413 in the future to include additional labeling requirements for certain specific new animal drugs as appropriate.

1. Approved or Conditionally Approved Corticosteroid-Containing New Animal Drugs for Oral, Injectable, and/or Ophthalmic Use

The proposed rule would move labeling requirements currently provided in § 510.410 relating to corticosteroid-containing new animal drugs intended for oral, injectable, and/or ophthalmic use to proposed § 201.413(a). We also propose a conforming amendment to remove current § 510.410.

Section 510.410 was originally issued by FDA in 1970 as § 135.101 (35 FR 11556, July 18, 1970) and provided

background information and established certain labeling requirements for corticosteroid animal drugs administered orally or parenterally. The regulation stated that such corticosteroid animal drugs must bear the veterinary prescription legend and meet the labeling requirements in § 201.105 for prescription new animal drugs. The regulation also required the labeling of these products to bear a warning statement regarding potential adverse reproductive effects to the treated animals when these drugs are administered during the last trimester of pregnancy, specifically premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The regulation was subsequently revised in 1972 (37 FR 24343, November 16, 1972) to address corticosteroid animal drugs for oral, injectable, and intramammary use. In 1984, FDA amended the regulation on labeling requirements for use of corticosteroid animal drugs again to add ophthalmic products, delete intramammary products, and to include an additional warning concerning certain potential congenital/teratogenic effects (49 FR 48535, December 13, 1984). Ophthalmic products were added to the regulation based on the results of a published study supporting the need for these warning statements for ophthalmic use corticosteroid drugs. Intramammary corticosteroid animal drugs were removed from the regulation because intramammary products no longer included steroids in their formulations.

The proposed rule would redesignate § 510.410 as proposed § 201.413(a) and revise its contents to remove some of the background information because we believe it is now well understood. Furthermore, we propose to update some of the warning statements to use more concise language. These animal drug products would continue to be subject to the labeling requirements for prescription new animal drugs. However, because the labeling requirements for approved or conditionally approved prescription new animal drugs would no longer be in § 201.105, we would update the citation to refer to the labeling requirements for prescription new animal drugs in proposed subpart H.

The proposed rule would require the warning statements for adverse reproductive effects to be included in the ''Animal Safety Warnings and Precautions'' subsection of labeling for approved or conditionally approved corticosteroid new animal drugs for oral, and/or injectable use (see proposed § 201.413(a)). For corticosteroid new animal drugs approved or conditionally approved for ophthalmic use, per this proposal, we may require these statements to also be included in the ''Animal Safety Warnings and Precautions'' subsection of labeling. For example, the warning statements might not be necessary for ophthalmic corticosteroid new animal drugs if data are provided to us that demonstrate the intended use is not associated with adverse reproductive effects in the treated animal.

2. Anthelmintic New Animal Drugs

The proposed rule would move labeling requirements currently provided in § 500.25 for approved or conditionally approved OTC anthelmintic new animal drugs to proposed § 201.413(b)(1). Labeling requirements currently provided in § 500.25 for OTC anthelmintic new animal drugs that are indexed would be moved to § 516.155 (21 CFR 516.155), ''Labeling of indexed drugs''. We also propose a conforming amendment to remove current § 500.25. Furthermore, the proposed rule would require that all approved or conditionally approved anthelmintic new animal drugs for use in sheep, goats, cattle, horses, swine, and/or poultry include statements on labeling on appropriate use of these drugs to minimize anthelmintic resistance development (see proposed § 201.413(b)(2)).

Section 500.25 was originally issued by FDA in 1974 as § 135.111 (39 FR 7165 at 7166, February 25, 1974) and required that labeling for anthelmintic animal drugs not carrying the prescription statement bear the following statement ''Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.'' Labeling of approved anthelmintic animal drugs not carrying the prescription statement were to be revised accordingly by February 25, 1975, and labeling of all subsequently approved non-prescription anthelmintic new animal drugs were to bear the statement. In 2007, § 500.25 was amended to add the labeling requirement for indexed non-prescription anthelmintic new animal drugs (72 FR 69108 at 69120, December 6, 2007).

The proposed rule would redesignate portions of § 500.25 for approved or conditionally approved OTC anthelmintic new animal drugs, including OTC anthelmintic new animal drugs for use in animal feeds, as proposed § 201.413(b)(1) and update some of its contents. VFD anthelmintic new animal drugs for use in or on animal feeds would be excluded from this requirement. The labeling statement would be required to be placed in the ''Additional Recommendations'' section of labeling. Reference to being able to revise labeling without prior approval would be removed because the labeling statement would be required for approval or conditional approval. Reference to an effective date of February 25, 1975 would be removed.

Portions of § 500.25 for indexed OTC anthelmintic new animal drugs would be redesignated as paragraph (c) in § 516.155, ''Labeling of indexed drugs''. Reference to an effective date of February 25, 1975 would be removed. The current § 516.155(c) would be redesignated as § 516.155(d).

The proposed rule would also require all approved or conditionally approved anthelmintic new animal drugs for use in sheep, goats, cattle, horses, swine, and/or poultry to include statements on their labeling providing information to end users on appropriate use of these drugs to minimize anthelmintic resistance development. FDA's Center for Veterinary Medicine held a public meeting on antiparasitic drug use and resistance in ruminants and equines on March 5 and 6, 2012. During that meeting, a panel of veterinary parasitology experts discussed the emerging problem of anthelmintic resistance cattle, horses, and especially small ruminants in the United States, contributing factors to resistance development, strategies to detect and manage anthelmintic resistance, and the importance of educating both veterinarians and other end users about how to detect and manage anthelmintic resistance. Since this meeting, published reports in the United States continue to support that anthelmintic resistance is spreading and is particularly concerning in grazing species (cattle, sheep, goats, and horses), but is also becoming a problem in swine and poultry.

It is in the interest of animal health to take a proactive approach to ensure that anthelmintics are used appropriately to help maintain the effectiveness of these drugs. Therefore, the proposed rule would require that all approved or conditionally approved anthelmintic new animal drugs for use in sheep, goats, cattle, horses, swine, and/or poultry include statements on their labeling providing information to end users on appropriate use of these drugs to minimize antiparasitic resistance development. These statements would include information on appropriate dosing, anthelmintic drug selection, effectiveness monitoring, the integration of anthelmintic drug use with other parasite management practices, and other information as needed (see

proposed § 201.413(b)(2)). The statements would be required in the ''Other Warnings'' subsection of labeling, and if applicable, additional statements may be required in the ''Dosage and Administration'' section of labeling for Rx anthelmintic new animal drugs, the ''Directions'' section of labeling for OTC anthelmintic new animal drugs, or the ''Feeding Directions'' section or subsection of labeling for anthelmintic new animal drugs for use in animal feeds. We would determine specific statements during review of the new animal drug and its labeling as part of the approval process and/or via guidance developed by FDA.

3. Approved or Conditionally Approved New Animal Drugs for Use in Horses

The proposed rule would require that all approved or conditionally approved new animal drugs for use in horses include in the ''Other Warnings'' subsection of labeling a statement advising against the use of the drug in certain horses (see proposed § 201.413(c)). Historically, drugs approved or conditionally approved for use in horses do not have tolerance levels established because FDA does not consider horses to be food-producing animals. Therefore, FDA currently does not require a human food safety evaluation of new animal drugs intended for use in horses. Because there is no human food safety evaluation of the new animal drug, FDA does not have the data needed to ensure that horses that have been treated with the drugs could safely be used for human consumption and sponsors may not label their drugs as appropriate for use in horses intended for use as human food. Proposed § 201.413(c) would require that all new animal drugs approved or conditionally approved for use in horses include a statement in the ''Other Warnings'' subsection of labeling advising against use of the drug in horses intended for human consumption.

I. Proposed Conforming Amendments

We also propose to amend the following sections:

- § 201.15 pertaining to foreign translations of labeling,
- § 201.100 pertaining to prescription drugs for human use,
- § 201.105 pertaining to prescription drugs for animal use,
- part 501 pertaining to animal food labeling,
- § 514.1 pertaining to new animal drug applications, and
- § 516.155 pertaining to labeling of indexed drugs.

Also, we propose to remove the following sections and incorporate their requirements in proposed new subpart H:

- § 500.25 pertaining to OTC anthelmintic drug use in animals, and
- § 510.410 pertaining to corticosteroids for oral, injectable, and ophthalmic use in animals.

We propose to remove the following sections:

- § 500.55 pertaining to the exemption of certain drug-labeling requirements, and
- §§ 510.105 and 510.106 pertaining to labeling of drugs for use in milk-producing animals.

The proposed rule would establish translation requirements for approved or conditionally approved new animal drug labeling that contains any representation of a foreign language in proposed § 201.404(i) and (j). Therefore, we propose a change to § 201.15, ''Drugs; prominence of required label statements.'' We propose adding paragraph (4) to § 201.15(c). Proposed paragraph (c)(4) would exempt approved or conditionally approved new animal drugs from the requirements established in § 201.15(c) and state that foreign translations of the labeling for approved or conditionally approved new animal drugs must comply with § 201.404(i) and (j).

The proposed rule would amend § 201.100, ''Prescription drugs for human use,'' in paragraph (d) to remove the words, ''and § 201.105(b)(2)'' from the introductory text. This conforming amendment would be in conjunction with conforming amendments proposed for § 201.105, ''Veterinary drugs'' (see discussion below), which includes the removal of § 201.105(f). Paragraph (f) provides labeling requirements for prescription drugs intended for both human and veterinary use.

Current § 201.105, entitled ''Veterinary drugs,'' provides requirements, including labeling requirements, for drugs subject to section 503(f)(1) of the FD&C Act, which are prescription drugs for animal use. These drugs include approved or conditionally approved prescription new animal drugs, prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species, and prescription animal drugs not subject to an approved or conditionally approved application or index listing. Section 201.100, ''Prescription drugs for human use,'' serves a similar purpose for prescription human drugs. The proposed rule would revise the title of § 201.105 to read ''Prescription drugs for animal use.'' This would clarify the scope of the section and be consistent with the title of its counterpart for human prescription drugs in § 201.100.

We propose minor editorial changes to update § 201.105(a), which provides requirements, other than labeling requirements, for prescription animal drugs.

To accommodate the proposed content and format requirements in proposed subpart H for labeling authorized in approved or conditionally approved new animal drug applications, the proposed rule would change § 201.105 to provide the labeling requirements for approved or conditionally approved prescription new animal drugs separately from the labeling requirements for prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species, and prescription animal drugs not subject to an approved or conditionally approved application or index listing. Accordingly, we propose to insert a new paragraph § 201.105(b) that would provide labeling requirements for prescription new animal drugs approved under section 512 of the FD&C Act or conditionally approved under section 571 of the FD&C Act. The provisions in the proposed paragraph § 201.105(c) would apply to prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species established under section 572 of the FD&C Act, and prescription animal drugs not subject to an approved or conditionally approved application or index listing.

The proposed rule would provide requirements for the labeling components for approved or conditionally approved prescription new animal drugs identified in proposed § 201.405 (see proposed § 201.105(b)(1)), which include labeling providing full prescribing information, labels, small labels, labeling for secondary containers that include a package insert, shipping labeling, and other approved labeling for prescription new animal drugs. Such labeling would be required to contain adequate information for use of the drug, including indications for use, dosages, routes of administration, frequency and duration of administration, and any relevant contraindications, warnings, precautions, and adverse reactions, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented (see proposed § 201.105(b)(1)(i)). The labeling

components identified in proposed § 201.405 also would be required to be the labeling authorized by the approved new animal drug application or conditionally approved new animal drug application for the prescription new animal drug (see proposed § 201.105(b)(1)(ii)).

These requirements for the labeling components identified in proposed § 201.405 would be consistent with requirements in current paragraph § 201.105(c) for labeling on or within the package from which the approved or conditionally approved prescription new animal drugs is dispensed. We also propose editorial revisions to use more current terminology regarding the types of information required to provide adequate information for use of the drug by veterinarians. These labeling components also would be required to comply with the applicable content and format requirements of proposed subpart H (see proposed § 201.105(b)(1)(iii)).

The exemption currently provided in § 201.105(c)(2) permits, upon written request to the Commissioner of Food and Drugs, the labeling information required by § 201.105(c)(1) (*i.e.,* adequate information for use) to be omitted from the dispensing container of prescription animal drugs for which the directions, hazards, warnings, and use information are commonly known to licensed veterinarians. Providing an exemption from the requirement that all prescription animal drugs must provide labeling that bears adequate information for use by veterinarians does not ensure safe and effective use of these drugs and is no longer warranted. Additional risks relating to the use of an animal drug may become known long after the drug is first marketed, even when veterinarians have become familiar with the directions, hazards, and warnings concerning its use. Moreover, in some cases, labeling may need to be revised to include additional safety information. Therefore, the proposed rule would revoke the exemption provided in current § 201.105(c)(2). As discussed below, we also propose to remove § 500.55, which lists the animal drugs to which this exemption has been applied.

The proposed rule would set forth requirements for any labeling, as defined in section 201(m) of the FD&C Act, for approved or conditionally approved prescription new animal drugs, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that provides or purports to provide information for use or prescribes, recommends, or suggests a dosage for use of the drug (see proposed § 201.105(b)(2)), consistent with the requirements in current § 201.105(d) for such prescription new animal drugs. Labeling, as defined in section 201(m) of the FD&C Act, means ''all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.'' Thus, labeling includes material such as promotional labeling, in addition to the labeling authorized in the approved new animal drug application or the conditionally approved new animal drug application. Such labeling that provides or purports to provide information or a dosage for the drug's use would be required to contain adequate information to ensure licensed veterinarians can use the drug safely and for the purposes for which the drug is intended, including all conditions for which the drug is advertised or represented. For the labeling of the approved or conditionally approved prescription animal drug to contain adequate information for use by veterinarians, proposed § 201.105(b)(2) would require such labeling to include the indications for use, dosages, routes of administration, frequency and duration of administration, and any relevant contraindications, warnings, precautions, and adverse reactions, and information relevant to compliance with the new animal drug provisions of the FD&C Act. It would also require the labeling components providing such information for use to be the same in language and emphasis as the labeling authorized by the approved or conditionally approved new animal drug application, and any other labeling components would have to be consistent with and not contrary to such authorized labeling (see proposed § 201.105(b)(2)(i)). The labeling would be required to contain the same information concerning the ingredients of the drug as appears on the labeling authorized by the approved new animal drug application or the conditionally approved new animal drug application (see proposed § 201.105(b)(2)(ii)).

We propose requirements for the label of prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species established under section 572 of the FD&C Act, and prescription animal drugs not subject to an approved or conditionally approved application or index listing, that are consistent with those currently provided in § 201.105(b) (see proposed § 201.105(c)(1)). The proposed rule includes requirements for the labeling on or within the package from which such drugs are to be dispensed that are consistent with the requirements currently provided in § 201.105(c) (see proposed § 201.105(c)(2)). In addition, the proposed rule includes editorial revisions to use more current terminology to identify the types of information that would need to be included on the labeling on or within the dispensing container in order to provide adequate information for use of such drugs by veterinarians (see proposed § 201.105(c)(2)). The proposed rule would revoke the exemption provided in current § 201.105(c)(2) for the reasons described previously.

Proposed § 201.105(c)(3) would require that any labeling, as defined in section 201(m) of the FD&C Act, for prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species, or prescription animal drugs not subject to an approved or conditionally approved application or an index listing, that is distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that provides information for use or a dosage for use of the drug contain adequate information for use of the drug by licensed veterinarians. This provision is consistent with the requirements currently provided in § 201.105(d) for these prescription animal drugs. In addition, all labeling for such prescription animal drugs, except labels and cartons, that contain information for use of the drug would be required to include the date of the issuance or latest revision of such labeling, consistent with the requirements currently provided in § 201.105(e) (see proposed § 201.105(c)(4)).

The proposed rule would replace the current proviso language in § 201.105(d)(2) relating to prescription animal drug *reminder-piece labeling* with a provision that is similar to the *reminder labeling* provision at § 201.100(f) (21 CFR 201.100(f)) for human prescription drugs (see proposed § 201.105(d)). Specifically, the proposed provision would replace the term *reminder-piece labeling* with the term *reminder labeling* and define *reminder labeling* for prescription animal drugs in a manner similar to how that term is defined for prescription human drugs. In the past, we have relied on the definition for reminder labeling in § 201.100(f) as a guide when reviewing such labeling because the current proviso language in § 201.105 lacks such a detailed definition. We propose to modify the definition for reminder labeling found at § 201.100(f) to establish a similar definition for prescription animal drugs. The proposed use of the term *reminder*

labeling for prescription animal drugs and the proposed inclusion of a definition for this term that is similar to the definition in § 201.100(f) is clearer and more accurate than the current definition for reminder-piece labeling (see proposed § 201.105(d)).

Current § 201.105(f) provides labeling requirements for prescription drugs intended for both human and veterinary use. The proposed rule would remove this provision, which was established in 1960 (as § 1.106(c)(6)); 25 FR 12592) and is now obsolete. In 1968, section 512 of the FD&C Act established separate approval requirements for new animal drugs, including their labeling.

The proposed rule would remove § 500.25, which contains labeling requirements for OTC anthelmintic new animal drugs. The requirements for the labeling of approved or conditionally approved OTC anthelminthic new animal drugs contained in current § 500.25 would be moved to proposed § 201.413(b)(1), ''Labeling requirements for certain approved or conditionally approved new animal drugs.'' This would further consolidate regulations pertaining to labeling of approved or conditionally approved new animal drugs. The requirements for the labeling of indexed OTC anthelminthic new animal drugs contained in current § 500.25 would be moved to § 516.155, ''Labeling of indexed drugs.''

To ensure the safe and effective use of new animal drugs, the proposed rule would remove from the provision found at § 500.55, ''Exemption from certain drug-labeling requirements,'' and proviso language at § 201.105(c)(2) that permits animal drug sponsors to receive an exemption from including certain labeling information required by § 201.105(c)(1) on the dispensing package for their products where the Commissioner of Food and Drugs has determined that such information is already commonly known to veterinarians. Under § 201.105(c)(1) of this Agency's regulations, the labeling on or within the dispensing package of prescription new animal drugs must have adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions, under which veterinarians licensed by law to administer the drug can use it safely and for the purposes for which the drug is intended, including all purposes for which the drug is advertised or represented. Section 201.105(c)(2) contains certain proviso language that permits the ''full disclosure'' labeling required by § 201.105(c)(1) to be omitted from the dispensing package of prescription new animal drugs if the directions, hazards, warnings, and use information are commonly known to veterinarians. The Commissioner of Food and Drugs has, upon written request, offered an opinion that such information may be omitted from the dispensing package for the prescription animal drugs listed in § 500.55. Only eight animal drugs have received such an exemption from providing the full disclosure labeling information otherwise required by § 201.105(c)(1).

The list of unapproved prescription animal drugs currently in § 500.55 that have received an exemption from providing full disclosure labeling meeting the requirements of § 201.105(c)(1) on their dispensing package was initially created in 1962. This list was added to a then-existing provision at 21 CFR 3.515 that permitted full disclosure labeling to be omitted from the dispensing package of certain prescription drugs for human use in cases where the Commissioner of Food and Drugs determined that directions, hazards, warnings, and use information for such drugs was commonly known to physicians (27 FR 5428, June 8, 1962). In 1971, when FDA issued regulations implementing the Animal Drug Amendments of 1968, the human and animal drug provisions were recodified in separate sections of FDA's regulations. As a result, the list of animal drugs exempt from the requirement to have full disclosure labeling on their dispensing package was moved to § 135.107 and the list of human prescription drugs exempt from similar labeling requirements was moved to § 201.160. In the mid-1970s, as part of the Agency's reorganization of its regulations, the animal drug list was moved again to § 500.55.

In 1979, FDA removed § 201.160, the human drug provision similar to § 500.55, because the Agency's experience had shown that risks from the use of a drug may be uncovered long after the drug is first marketed, even for long-used drugs for which physicians had become familiar with the directions, hazards, and warnings concerning their use. FDA concluded that current full disclosure labeling should be provided for all human prescription drugs to ensure that physicians have the information they need to use these drugs safely. For similar reasons, full disclosure labeling is needed for all prescription new animal drugs to ensure veterinarians are able to use these products safely and effectively. In addition, none of the eight products listed in § 500.55 received FDA approval for the uses in animals for which they were generally employed by veterinarians at the time the list of exempt drugs was initially established in 1962, and several are no longer used in veterinary medicine. Therefore, we propose to remove § 500.55 and the proviso language at § 201.105(c)(2).

In part 501 subpart A, we propose to add a new section, § 501.19, ''Animal food; labeling of animal food containing new animal drugs.'' Proposed § 501.19 would require labeling of animal food containing an approved or conditionally approved new animal drug to comply with proposed § 201.409. The requirements in part 501 would apply only as specified in proposed § 201.409.

The proposed rule would remove § 510.105, ''Labeling of drugs for use in milk-producing animals'', and § 510.106, ''Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals'', which provide statements required to appear on the labeling of such drugs for use in milk-producing animals. The requirements in proposed § § 201.405(a)(10)(i), 201.407(a)(7)(i), and 201.409(a)(10)(i) would supersede the requirements in §§ 510.105 and 510.106.

Section 510.105 was originally issued by FDA in 1960 as 21 CFR 3.18 (25 FR 8321, August 31, 1960) and was recodified as § 135.103 (21 CFR 135.103) in 1971 (36 FR 18375 at 18393, September 14, 1971). In 1975 § 135.103 was redesignated as § 510.105 (40 FR 13802, March 27, 1975).

Section 510.106 was originally issued by FDA in 1960 as § 146.14 (21 CFR 146.14) (25 FR 8321 at 8322, August 31, 1960). In 1964, § 146.14 was redesignated as § 148.5 (21 CFR 148.5) (29 FR 15672, November 21, 1964) and subsequently amended in 1965 (30 FR 7040 at 7041, May 26, 1965) to update the warning statements. In 1975 § 148.5 was redesignated as § 510.106 (40 FR 13802, March 27, 1975).

Both §§ 510.105 and 510.106 were amended in 1998 to update the warning statements in those provisions to reflect current practices in the dairy industry (63 FR 32978, June 17, 1998).

The proposed rule would remove §§ 510.105 and 510.106 because the labeling requirements proposed for the subsection entitled ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods'' would supersede such requirements in §§ 510.105 and 510.106. The labeling requirements for the proposed ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods'' subsection would provide flexibility to have more targeted and informative statements with respect to human food safety warnings, including

milk discard times, withdrawal periods, and residue warning statements for the labeling of all new animal drugs intended for use in food-producing animals (see proposed §§ 201.405(a)(10)(i), 201.407(a)(7)(i), and 201.409(a)(10)(i)).

The proposed rule would remove § 510.410. The requirements in current § 510.410 would be moved to proposed § 201.413, ''Labeling requirements for certain approved or conditionally approved new animal drugs.'' The warning language would be clarified and updated in proposed § 201.413(a). This would further consolidate regulations pertaining to labeling of approved or conditionally approved new animal drugs.

The proposed rule would amend § 514.1, which describes the requirements for applications for new animal drugs. Current § 514.1(b)(3) describes the labeling that must be included in a new animal drug application. Paragraphs (ii) through (vi) of current § 514.1(b)(3) describe the labeling required in a new animal drug application for prescription and nonprescription new animal drugs and new animal drugs intended for use in the manufacture of medicated feeds.

The proposed rule would insert a paragraph after § 514.1(b)(3)(i) to indicate that the content and format of all proposed labeling must comply with subpart H of part 201 of this chapter.

Paragraphs (ii) through (vi) of § 514.1(b)(3) would be redesignated as paragraphs (iii) through (vii). The current text ''prescription veterinary drugs'' in redesignated paragraphs (iv) and (vii) would be changed to ''prescription new animal drugs'' to be consistent with the text used in proposed subpart H.

VI. Proposed Effective/Compliance Dates

If finalized, sponsors of new animal drugs would need to comply with these proposed regulations within 6 years of the effective date of the final rule, according to the compliance schedule provided in the General Requirements section of this proposed rule, discussed in section V.C. The compliance schedule is based on application number, with approved NADAs with higher application numbers having the earliest compliance date because they are more recently approved and therefore likely to need the fewest labeling revisions. The 6-year compliance period would begin on the effective date of the final rule (see proposed § 201.404(a)(4)).

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 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 proposed rule is not a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because net annualized compliance costs of the proposed rule are less than 2 percent of average annual revenues for the smallest firms in the industry, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would require that sponsors follow specific content and format requirements for labeling of approved or conditionally approved new animal drugs. A comprehensive set of standardized requirements for the content and format of information on labeling of such drugs currently does not exist. Veterinarians, pet owners, livestock owners, and other users of new animal drugs may more easily locate the information they need with standardized labeling.

We quantify potential cost savings to industry and FDA from a reduction in the quantity and time burden of new animal drug labeling amendments and informal communications related to new animal drug labeling. There may be additional benefits to users of approved or conditionally approved new animal drugs from greater predictability and ease of reading new animal drug labeling in the form of time saved searching for content, which we are unable to quantify. Additionally, animal or human health benefits may result from reductions in medication errors or improvements in adverse event reporting, which we cannot quantify.

We expect that new animal drug sponsors would incur one-time costs to read and understand the rule, revise standard operating procedures (SOPs) related to labeling, and train employees on the revised SOPs. New animal drug sponsors would also bear costs to update labeling and prepare supplemental labeling applications to conform to the proposed requirements. FDA would incur costs to review these supplemental applications.

We summarize the quantified benefits and costs in table 2. We estimate that the annualized benefits over 10 years would range from $0.143 million to $0.243 million at a 2 percent discount rate, with a primary estimate of $0.193 million. The annualized costs would range from $2.16 million to $2.77 million at a 2 percent discount rate, with a primary estimate of $2.45 million.

The present value of total benefits over 10 years would range from $1.31 million to $2.23 million at a 2 percent discount rate, with a primary estimate of $1.77 million. At a 2 percent discount rate, the present value of total costs would range from $19.78 million to $25.38 million, with a primary estimate of $22.48 million.

TABLE 2—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE
[Millions of 2022 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate	Time horizon	Notes (e.g., Risk assumptions; source citations; whether inclusion of capital effects differs across low, primary, high estimates; etc.)
Benefits:							
Annualized monetized benefits	$0.193	$0.143	$0.243	2022	2	10	Cost savings to industry and FDA.
Annualized quantified, but non-monetized, benefits.	.....	.....	.....	.....	.....	.....	
Unquantified benefits	Information search cost savings to users of new animal drugs and potential benefits to animal or human health.						
COSTS:							
Annualized monetized costs	2.45	2.16	2.77	2022	2	10	
Annualized quantified, but non-monetized, costs	.....	.....	.....	.....	.....	.....	
Unquantified costs	.....	.....	.....	.....	.....	.....	
Transfers:							
Annualized monetized Federal budgetary transfers.	.....	.....	.....	.....	.....	.....	
Bearers of transfer gain and loss?	.....	.....	.....	.....	.....	.....	
Other annualized monetized transfers	.....	.....	.....	.....	.....	.....	
Bearers of transfer gain and loss?	.....	.....	.....	.....	.....	.....	
Net Benefits:							
Annualized monetized net benefits	−2.26	−2.02	−2.53	2022	2	10	

Category	Effects	Notes
Effects on State, local, or Tribal governments	None.	
Effects on small businesses	Quantified effects of less than 2 percent of average annual revenues for the smallest firms.	
Effects on wages	None.	
Effects on growth	None.	

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 2) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VIII. Analysis of Environmental Impact

The Agency has determined under § 25.30(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 proposed rule contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Reporting Associated With New Animal Drug Applications and Veterinary Master Files; OMB control number 0910–0032—Revision.

Description: The proposed rule, if finalized, would revise the existing requirements for the content and format of labeling for approved or conditionally approved new animal drugs that sponsors submit as part of NADAs or CNADAs, respectively. The proposed rule would also place labeling requirements that are specific to approved or conditionally approved new animal drugs in a single location in the CFR. The proposed rule would apply to the labeling of both Rx and OTC new animal drugs, as well as new animal drugs for use in animal feeds.

The proposed regulations would provide the following for the content and format elements of labeling for approved or conditionally approved new animal drugs:

Description of Respondents: Respondents include persons developing, manufacturing, and/or researching new animal drugs, commonly referred to as new animal drug sponsors.

We estimate the burden of the information collection as follows:

TABLE 3—ESTIMATED ONE-TIME REPORTING BURDEN

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
514.8 and 514.8(c)(2); supplements and changes to an approved application	66	[1] 12.55	[2] 828	20	16,560

[1] Decimal rounded up.
[2] Decimal rounded down.

To ease the burden of the information collection on respondents, we have established a 6-year implementation period. We estimate 828 supplemental labeling applications of approved and marketed new animal drugs over the course of 6 years to comply with the labeling regulations, if finalized. Based on internal data, there were 78 unique firms with an approved or conditionally approved new animal drug application (sponsors) in September 2023. Sixty-six of these sponsors currently had an approved and marketed new animal drug. We assume 828 submissions regarding supplements and changes to an application for an approved and marketed new animal drug, for an average of 12.55 submissions per respondent. We further assume it takes an average of 20 hours to prepare each submission for a total of 16,560 hours.

TABLE 4—ESTIMATED ONE-TIME RECORDKEEPING BURDEN

Activity	Number of Recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Reading and understanding the rule	156	1	156	6	936
Writing new labeling SOPs	156	1	156	2.14	[1] 334
Training	156	1	156	0.89	[1] 139
Total					1,409

[1] Decimal rounded up.

We estimate that approved new animal drug sponsors will incur one-time burden attributable to reading and understanding the rule, revising SOPs related to labeling, and training employees on the revised SOPs. We estimate the average time to read and understand the proposed rule is 6 hours ($156 \times 6 = 936$ hours). We estimate that small businesses will spend 4 hours and large business will spend 8 hours revising SOPs related to labeling. Based on data from the 2017 Statistics of U.S. Businesses, there are 72 small business entities and 6 large business entities. $((72 \times 4) + (6 \times 8) \div 156 = 2.14$ hours per record). We also estimate that small businesses will spend 1 hour and large businesses will spend 12 hours to train employees on the revised SOPs $((72 \times 1) + (6 \times 12) \div 156 = 0.89$ hours per record). We assume at least two recordkeepers per drug sponsor.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132: Federalism. The Order requires Federal Agencies to examine actions carefully to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, ''policies that have federalism implications'' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Section 4(a) of the Order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The sole statutory provision giving preemptive effect to this proposed rule is section 751 of the FD&C Act (21 U.S.C. 379r), which would apply only with respect to nonprescription animal drugs. There are no express preemption provisions of the FD&C Act applicable to prescription animal drugs.

We have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effect of this proposed rule, if finalized, would be consistent with Executive Order 13132. Through publication of this proposed rule, we are providing notice and an opportunity for State and local officials to comment on this rulemaking.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would 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. The

Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references are on display in 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, Preliminary Regulatory Impact, Initial Regulatory Flexibility, and Unfunded Mandates Reform Act Analyses, 2023; Docket No. FDA–2023–N–5160; *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and Recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

21 CFR Part 501

Animal foods, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 514 and 516

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, we propose that 21 CFR parts 201, 500, 501, 510, 514, and 516 be amended as follows:

PART 201—LABELING

■ 1. The authority citation for part 201 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 354, 355, 358, 360, 360b, 360ccc, 360ccc–1, 360ee, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. In § 201.15, add paragraph (c)(4) to read as follows:

§ 201.15 Drugs; prominence of required label statements.

* * * * *

(c) * * *

(4) Approved or conditionally approved new animal drugs are exempted from the requirements in paragraph (c). Foreign language translations of the labeling for approved or conditionally approved new animal drugs must comply with § 201.404(i) and (j).

§ 201.100 [Amended].

■ 3. In § 201.100, in paragraph (d) introductory text remove the words, ''and § 201.105(b)(2)''.

■ 4. Revise § 201.105 to read as follows:

§ 201.105 Prescription drugs for animal use.

A drug subject to the requirements of section 503(f)(1) of the Federal Food, Drug, and Cosmetic Act is exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if all the following conditions are met:

(a) The prescription animal drug is:

(1)(i) In the possession of a person, or the person's agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of drugs that are to be used only by or on the prescription or other order of a licensed veterinarian; or

(ii) In the possession of a retail, hospital, or clinic pharmacy, or other person authorized under State law to dispense prescription animal drugs, who is regularly and lawfully engaged in dispensing drugs that are to be used only by or on the prescription or other order of a licensed veterinarian; or

(iii) In the possession of a licensed veterinarian for use in the course of his or her professional practice; and

(2) To be dispensed in accordance with section 503(f) of the Federal Food, Drug, and Cosmetic Act.

(b) For prescription new animal drugs approved under section 512 of the Federal Food, Drug, and Cosmetic Act or conditionally approved under section 571 of the Federal Food, Drug, and Cosmetic Act:

(1) The labeling components identified in § 201.405 for the prescription new animal drug:

(i) Contain adequate information for its use, including indications for use, dosages, routes of administration, frequency and duration of administration, and any relevant contraindications, warnings, precautions, and adverse reactions, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented;

(ii) Are authorized by the approved new animal drug application or the conditionally approved new animal drug application for the prescription new animal drug; and

(iii) Comply with the applicable content and format requirements of subpart H of this part.

(2) Any labeling, as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act, for the approved or conditionally approved prescription new animal drug, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that provides or purports to provide information for its use or a dosage for its use contains:

(i) Adequate information for such use, including indications for use, dosages, routes of administration, frequency and duration of administration, and any relevant contraindications, warnings, precautions, and adverse reactions, and information relevant to compliance with the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented, and the labeling components providing such information for use are the same in language and emphasis as labeling authorized by the approved new animal drug application or the conditionally approved new animal drug application, and any other labeling components are consistent with and not contrary to such authorized labeling; and

(ii) The same information concerning the ingredients of the drug as appears on the labeling authorized by the approved new animal drug application or the conditionally approved new animal drug application.

(c) For prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species established under section 572 of the Federal Food, Drug, and Cosmetic Act, or prescription animal drugs not subject to an approved or conditionally approved application or indexed listing:

(1) The label of the drug bears:

(i) The statement, ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian'';

(ii) The recommended or usual dosage;

(iii) The route of administration, if it is not for oral use;

(iv) The quantity or proportion of each active ingredient as well as the information required by section 502(e)

of the Federal Food, Drug, and Cosmetic Act; and

(v) If it is for other than oral use, the names of all inactive ingredients, except that:

(A) Flavorings and perfumes may be designated as such without naming their components;

(B) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in subchapter A of this chapter; and

(C) Trace amounts of harmless substances added solely for individual product identification need not be named.

(vi) If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection, it need not be named.

(vii) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug.

(viii) In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all of the information required by paragraph (c)(1) of this section, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraphs (c)(1)(ii), (iii), (v), and (vi) of this section may be contained in other labeling on or within the package from which the drug is to be so dispensed, and the information referred to in paragraph (c)(1)(i) of this section may be placed on such outer container only, and the information required by paragraph (c)(1)(vii) of this section may be placed on the crimp of the dispensing tube.

(2) The labeling on or within the package from which the drug is to be dispensed:

(i) Bears adequate information for its use, including indications for use, dosages, routes of administration, frequency and duration of administration, and any relevant contraindications, warnings, precautions, and adverse reactions, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and

(ii) For prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species established under section 572 of the Federal Food, Drug, and Cosmetic Act, the labeling bearing such information is the labeling contained in the index listing.

(3) Any labeling, as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that provides or purports to provide information for use or which prescribes, recommends, or suggests a dosage for the use of the drug (other than dose information required by paragraph (c)(1)(ii) of this section) contains:

(i) Adequate information for such use, including indications for use, dosages, routes of administration, frequency and duration of administration, and any relevant contraindications, warnings, precautions, and adverse reactions, including information relevant to compliance with the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; for prescription new animal drugs listed in the index of legally marketed unapproved new animal drugs for minor species established under section 572 of the Federal Food, Drug, and Cosmetic Act, the labeling components providing such information are the same in language and emphasis as labeling indexed under the provisions of section 572 of the Federal Food, Drug, and Cosmetic Act, and any other labeling components are consistent with and not contrary to such indexed labeling; and

(ii) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed.

(4) All labeling, except labels and cartons, bearing information for use of the drug also bears the date of the issuance or the date of the latest revision of such labeling.

(d) Reminder labeling, which calls attention to the name of the prescription animal drug product but does not include indications or dosage recommendations for use of the drug product, is exempted from the provisions of paragraphs (b) and (c) of this section. This reminder labeling must contain only the proprietary name of the drug product, if any; the established name of the drug product, if any; the established name of each active ingredient in the drug product; and, optionally, information relating to quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the drug product. If the Commissioner finds that there is evidence of significant incidence of fatalities or serious injury associated with the use of a particular prescription animal drug, the Commissioner may withdraw this exemption by so notifying the manufacturer, packer, or distributor of the drug by letter. Reminder labeling, other than price lists and catalogs solely intended to convey price information, is not permitted for a prescription animal drug product whose labeling contains a boxed warning relating to a serious hazard associated with the use of the drug product.

■ 5. Add subpart H, consisting of §§ 201.401 through 201.413, to read as follows:

Subpart H—Labeling Requirements for Approved or Conditionally Approved New Animal Drugs

Sec.

201.401 Scope.
201.403 Definitions.
201.404 General requirements.
201.405 Content and format for prescription new animal drug labeling.
201.407 Content and format for over-the-counter (OTC) new animal drug labeling.
201.409 Content and format of labeling for new animal drugs for use in animal feeds.
201.411 Exemptions from labeling requirements for approved or conditionally approved new animal drugs.
201.413 Labeling requirements for certain approved or conditionally approved new animal drugs.

Subpart H—Labeling Requirements for Approved or Conditionally Approved New Animal Drugs

§ 201.401 Scope.

(a) This subpart establishes requirements for content and format of labeling for the following categories of prescription (Rx) new animal drugs, over-the-counter (OTC) new animal drugs other than those for use in animal feeds in accordance with part 558 of this chapter, and new animal drugs for use in animal feeds that are subject to part 558 of this chapter, including veterinary feed directive (VFD) drugs:

(1) New animal drugs that are the subject of a new animal drug application (NADA) approved or submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act;

(2) New animal drugs that are the subject of an application for conditional

approval (CNADA) conditionally approved or submitted pursuant to section 571 of the Federal Food, Drug, and Cosmetic Act;

(3) Generic new animal drugs that are the subject of an abbreviated new animal drug application (ANADA) approved or submitted pursuant to section 512(n) of the Federal Food, Drug, and Cosmetic Act that references a new animal drug for which the NADA has been voluntarily withdrawn for reasons other than safety or effectiveness, or that references a new animal drug for which the NADA has been withdrawn on the basis of one or more of the grounds included under section 512(e) of the Federal Food, Drug, and Cosmetic Act and for which the generic new animal drug's approval was not affected by the withdrawal; and

(4) New animal drugs for use in proprietary medicated feeds for which the labeling is maintained in a Veterinary Master File (VMF). Proprietary medicated feeds for which the labeling is maintained in an NADA or CNADA are included within the categories of drugs described in paragraphs (a)(1) and (2) of this section.

(b) The provisions of this subpart apply to the applications described in paragraphs (a)(1) through (4) of this section for new animal drugs that are approved before the [EFFECTIVE DATE OF THE FINAL RULE], pending on the [EFFECTIVE DATE OF THE FINAL RULE], or submitted on or after the [EFFECTIVE DATE OF THE FINAL RULE], in accordance with the schedule in § 201.404(a)(4).

(c) Any new animal drug subject to this subpart that does not fully comply with the applicable requirements of this subpart in accordance with the schedule in § 201.404(a)(4) is deemed to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and, if that drug is a VFD drug, also under section 504(b) of the Federal Food, Drug, and Cosmetic Act.

(d) The provisions of this subpart do not apply to:

(1) Legally marketed unapproved new animal drugs for minor species that are indexed in accordance with section 572 of the Federal Food, Drug, and Cosmetic Act;

(2) Heritable intentional genomic alterations in animals; and

(3) Promotional labeling or advertising.

§ 201.403 Definitions.

The following definitions apply to this subpart H.

Active ingredient has the same meaning as given in § 210.3(b)(7) of this chapter.

Active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

Adverse drug experience has the same meaning as given in § 514.3 of this chapter.

Adverse reaction means an undesirable effect, reasonably associated with the use of the drug product, that may occur as part of the pharmacological action of the drug or that may be unpredictable in occurrence.

ANADA has the same meaning as given in § 514.3 of this chapter.

Boxed warning means certain contraindications or serious warnings, particularly those that may lead to death or serious injury to animals or humans that must be presented in a box on labeling. The box and its contents must be bolded. The boxed warning is ordinarily based on data from the target animal, but data from other species may also be used.

Contraindication means any situation in which the new animal drug should not be used because the risk of use (*e.g.,* certain potentially fatal adverse reactions) clearly outweighs any possible benefit to the animal. Those situations may include use of the drug in animals that, because of their particular species, class, breed, age, sex, concomitant therapy, disease state, or other condition such as pregnancy or lactation, have a substantial risk of being harmed by the drug and for which no potential benefit makes the risk acceptable. Contraindications include only known hazards.

Drug product has the same meaning as given in § 210.3(b)(4) of this chapter.

Environmental warning means a warning that identifies any potential hazard to the human environment associated with the use of the new animal drug.

Established name has the same meaning as given in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act.

Extralabel use has the same meaning as given in § 530.3(a) of this chapter.

Field study means a type of adequate and well-controlled study designed to assess the effectiveness and/or safety of a new animal drug in the target animal under conditions that closely approximate the actual conditions of use.

Free-choice medicated feed has the same meaning as given in § 510.455(a) of this chapter.

Full prescribing information means all information necessary for the safe and effective use of a Rx new animal drug.

Full product information means all information necessary for the safe and effective use of an OTC new animal drug.

Immediate container means the container in contact with the new animal drug. The term ''immediate container'' does not include package liners (section 201(l) of the Federal Food, Drug, and Cosmetic Act).

Inactive ingredient has the same meaning as given in § 210.3(b)(8) of this chapter.

Indication means the use for which the new animal drug is approved or conditionally approved.

Label has the same meaning as given in section 201(k) of the Federal Food, Drug, and Cosmetic Act.

Labeling has the same meaning as given in section 201(m) of the Federal Food, Drug, and Cosmetic Act.

Lot number, control number, or *batch number* has the same meaning as given in § 210.3(b)(11) of this chapter.

Milk discard time means the interval between the time of the last administration of a new animal drug and the time when the milk can be safely consumed.

NADA has the same meaning as given in § 514.3 of this chapter.

New animal drug has the same meaning as given in section 201(v) of the Federal Food, Drug, and Cosmetic Act.

Package insert means a labeling component that contains full prescribing information for Rx new animal drugs or full product information for OTC new animal drugs and is included with the immediate container or secondary container or is attached to the label.

Precaution means any special care to be exercised for safe and effective use of the new animal drug. This may include recommended screening, monitoring, or diagnostic tests.

Representative Type B medicated feed labeling means template labeling (also known as ''Blue Bird labels,'' 64 FR 63197, November 19, 1999) approved by FDA as part of the new animal drug application or an application for conditional approval for a Type A medicated article for the preparation of final printed labels (for medicated feed bags) or labeling (accompanying bulk medicated feed) for Type B medicated feeds containing the new animal drug. Representative Type B medicated feed labeling provides the minimum

information that must be included on the final printed labels or labeling for Type B medicated feeds.

Representative Type C medicated feed labeling means template labeling (also known as ''Blue Bird labels,'' 64 FR 63197, November 19, 1999) approved by FDA as part of the new animal drug application or an application for conditional approval for a Type A medicated article or proprietary Type B medicated feed for the preparation of final printed labels (for medicated feed bags) or labeling (accompanying bulk medicated feed) for Type C medicated feeds containing the new animal drug. Representative Type C medicated feed labeling provides the minimum information that must be included on the final printed labels or labeling for Type C medicated feeds.

Residue warning statement means a statement that warns against the use of the new animal drug in animals for which the withdrawal period and/or milk discard time has not been determined, and/or provides other information to prevent illegal drug residues in food products from animals treated with the new animal drug.

Secondary container means the packaging that surrounds the immediate container for a new animal drug.

Shipping labeling means labeling associated with the outermost carton containing immediate containers, secondary containers, and/or multiple unit (multi-unit) cartons of a new animal drug and intended for shipment, but not display, of the product.

Small label means a label on an immediate container for a new animal drug that has insufficient space to accommodate the information required for a label by § 201.405(b) for Rx new animal drugs or § 201.407(b) for OTC new animal drugs.

Sponsor has the same meaning as given in § 510.3(k) of this chapter.

Strength has the same meaning as given in § 210.3(b)(16) of this chapter.

Target animal means the species, or collection of species, of animals, and, if applicable, the specific subset(s) of animals (*e.g.,* life stage, production class, age, gender) for which the new animal drug is approved or conditionally approved.

Type A medicated article has the same meaning as given in § 558.3(b)(2) of this chapter.

Type B medicated feed has the same meaning as given in § 558.3(b)(3) of this chapter.

Type C medicated feed has the same meaning as given in § 558.3(b)(4) of this chapter.

User safety warning means a warning that identifies any serious adverse reaction or potential hazard to human health associated with human exposure during use of a new animal drug via contact, inhalation, ingestion, injection, or by other means.

Veterinary feed directive (VFD) has the same meaning as given in § 558.3(b)(7) of this chapter.

VFD drug has the same meaning as given in § 558.3(b)(6) of this chapter.

Warning means any serious adverse reaction or potential hazard associated with the use of the new animal drug.

Withdrawal period means the interval between the time of the last administration of a new animal drug and the time when the animal can be safely slaughtered for food.

§ 201.404 General requirements.

(a) The labeling of a new animal drug subject to these regulations as identified in § 201.401(a):

(1) Must conform to an application approved under section 512 of the Federal Food, Drug, and Cosmetic Act or conditionally approved under section 571 of the Federal Food, Drug, and Cosmetic Act.

(2) Must be informative and accurate and neither promotional in tone nor false or misleading in any particular.

(3) Must be updated if new information becomes available that causes the labeling to become inaccurate, false, or misleading, in accordance with § 514.8 of this chapter.

(4) Must conform to this subpart in accordance with the earliest applicable compliance date provided in the following schedule, unless paragraphs (b), (c), or (d) of this section are applicable.

TABLE 1 TO PARAGRAPH (a)(4)

Application No. and/or status	All conforming labeling must be submitted:
(i) NADA, CNADA, or a supplement to an NADA or CNADA subject to § 514.8(c)(2) submitted after [effective date of the final rule plus 180 days].	As part of the application or supplemental application.
(ii) NADA, CNADA, or a supplement to an NADA or CNADA subject to § 514.8(c)(2) pending on [effective date of the final rule] or submitted between [effective date of the final rule] and [effective date of the final rule plus 180 days].	As part of the application or supplemental application; or, as a supplement to an approved application or supplemental application no later than 180 days after the approval date of the application or supplemental application.
(iii) NADA number 141–300 or greater and originally approved before [effective date of the final rule]; or ANADA that references an NADA (1) voluntarily withdrawn for reasons other than safety and effectiveness, or (2) withdrawn under section 512(e) of the Federal Food, Drug, and Cosmetic Act and the ANADA's approval was not affected by the withdrawal.	As a supplement to an approved application between [effective date of the final rule plus 1 year] and [effective date of the final rule plus 2 years].
(iv) NADA number 141–000 to 141–299	As a supplement to an approved application between [effective date of the final rule plus 2 years] and [effective date of the final rule plus 3 years].
(v) NADA number 115–000 to 140–999	As a supplement to an approved application between [effective date of the final rule plus 3 years] and [effective date of the final rule plus 4 years].
(vi) NADA number 45–000 to 114–999	As a supplement to an approved application between [effective date of the final rule plus 4 years] and [effective date of the final rule plus 5 years].
(vii) NADA number 1 to 44–999	As a supplement to an approved application between [effective date of the final rule plus 5 years] and [effective date of the final rule plus 6 years].

(b) For proprietary Type B or Type C medicated feeds in which the underlying data and labeling are maintained in a VMF, a submission containing the conforming labeling must be made to the VMF within 180 days after all conforming labeling has been approved for the NADA or CNADA that is the approved or conditionally approved source of the new animal drug used to manufacture the proprietary medicated feed.

(c) Unless a supplement subject to § 514.8(c)(2) of this chapter is submitted to a CNADA after the [effective date of the final rule], new animal drugs conditionally approved before [effective date of the final rule] are not required to conform to this subpart until an application for full approval is submitted.

(d) For combination new animal drugs subject to section 512(d)(4) of the Federal Food, Drug, and Cosmetic Act that are approved for use in animal feed or drinking water on or before [effective date of the final rule], a supplement containing the conforming labeling for the combination new animal drug must be submitted within 180 days after all conforming labeling has been approved for the individual new animal drugs in the combination.

(e) In those circumstances where it may not be clear how a requirement in this subpart applies to a particular new animal drug, or whether it applies, the final determination will be made by FDA.

(f) When submitting labeling for the purposes of conforming to the requirements of subpart H according to the schedule in paragraph (a)(4) of this section, all labeling components for the approved or conditionally approved new animal drug must be provided in one submission. FDA will refuse to file labeling submissions intended to conform to this subpart if they are incomplete.

(g) All labeling for an approved or conditionally approved new animal drug must comply with the general formatting requirements described in this paragraph in addition to all content and formatting requirements described in this subpart.

(1) Placement of the established name relative to the proprietary name on labeling for approved or conditionally approved Rx new animal drugs must comply with § 201.10(g)(1). Size and prominence of the established name relative to the proprietary name must comply with section 502(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act and § 201.10(g)(2).

(2) Placement, size, and prominence of the established name relative to the proprietary name on the labeling for approved or conditionally approved OTC new animal drugs and the labeling for approved or conditionally approved new animal drugs for use in animal feeds (Type A medicated article label, proprietary Type B medicated feed label, proprietary Type C medicated feed label, other approved labeling associated with a Type A medicated article), excluding representative Type B and Type C medicated feed labeling, must comply with the following requirements:

(i) The proprietary name of the new animal drug must be accompanied by the established name each time the proprietary name is featured on the labeling, except in running text. Running text includes detailed information such as found in warnings and directions. On any panel or page of a component of labeling in which the proprietary name is not featured elsewhere but is used in the running text, the established name must be placed in conjunction with the proprietary name at least with the first presentation of the proprietary name in running text.

(ii) Where the established name accompanies the proprietary name, it must be placed directly to the right of, or directly below, the proprietary name. Except for trademark symbols associated with the proprietary name, the proprietary name and the established name must not be separated by placement of intervening matter that, in any way, detracts from, obfuscates, or de-emphasizes the established name of the product, or obscures the relationship between the proprietary name and the established name. The established name must be presented entirely within parentheses.

(iii) Except in running text, where the established name accompanies the proprietary name, the smallest letter of the established name (upper or lower case letters) must be printed in letters at least half the size of the largest letter of the proprietary name (upper or lower case letters). Within running text, the established name accompanying the proprietary name must be printed in letters the same size of the letters in the proprietary name (upper and lower case letters). The prominence of the established name must be consistent with the prominence of the proprietary name, taking into account all pertinent factors including typography, layout, contrast, and other printing features.

(3) For representative Type B and Type C medicated feed labeling for approved or conditionally approved new animal drugs for use in animal feeds, the established name of the Type B or Type C medicated feed presented below the description of the Type B or Type C medicated feed must comply with the following requirements:

(i) The established name must be presented directly below the description of the Type B or Type C medicated feed and must not be separated by placement of intervening matter.

(ii) The established name must be printed in lower case letters except for ''Type B'' or ''Type C''.

(iii) The established name must be printed in non-bold font of the same size letters as the name of the Type B or Type C medicated feed (upper and lower case letters).

(iv) The established name must be presented entirely within parentheses.

(4) All labeling text and type style must be easy to read, and letters must not touch.

(5) Running text, section headings, and subsection headings on package inserts and representative Type B and Type C medicated feed labeling must be in black and on a white background and use a single type style. For other labeling components, other color combinations may be used if there is sufficient contrast between text and the background colors to ensure readability of the text.

(6) Representative Type B and Type C medicated feed labeling must not contain any logos, graphics, or designs other than illustrations or tables that FDA determines are necessary for proper use of the medicated feed. For other labeling components for approved or conditionally approved new animal drugs, in accordance with § 201.15(b)(1), graphics or designs associated with the labeling must not take up space needed for information required by this subpart. In accordance with paragraph (a)(2) of this section, graphics or diagrams must not be promotional in tone. If graphics are incorporated into the background, for any text appearing over the graphics, there must be sufficient contrast between the text and the graphics colors to ensure readability of the text. The use of compressed arrows on labeling is limited to the subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods,'' in accordance with paragraph (g)(8)(iii) of this section.

(7) The following minimum letter height or type size must be used for specific components of labeling, subject to the provisions of paragraph (g)(2) of this section:

(i) Immediate container label, secondary container labeling, package inserts, and labeling of multiple unit cartons and display cartons: 8 points.

(ii) Small label: 6 points.

(iii) Type A medicated article label, representative Type B medicated feed labeling, representative Type C medicated feed labeling, proprietary Type B medicated feed label, and proprietary Type C medicated feed label: 10 points.

(iv) Additional labeling for Rx new animal drugs that is to be provided to the animal owner: 12 points.

(v) Shipping labeling for Rx and OTC new animal drugs and other approved labeling for Type A medicated articles: 16 points.

(8) Section headings and subsection headings must be formatted as follows:

(i) All section headings and subsection headings must be in bold type that prominently distinguishes them from other approved labeling information.

(ii) Section headings must be either left justified or centered.

(iii) For the subsection entitled either ''Withdrawal Periods and Residue Warnings'' or ''Withdrawal Periods,'' the subsection heading, and the contents of the subsection, must be centered within compressed arrows.

(iv) All other subsection headings must be left justified.

(h) If the National Drug Code (NDC) is included on labeling, it must appear in accordance with § 207.33 of this chapter.

(i) All words, statements, and other information required on the labeling for approved or conditionally approved new animal drugs must appear in the English language. Additional translations of labeling for approved or conditionally approved new animal drugs into foreign languages must comply with the following requirements:

(1) For approved or conditionally approved Rx new animal drugs, if a labeling component contains any section or wording translated into a foreign language, then the entire full prescribing information must be translated into the foreign language and must comply with the format and content requirements in § 201.405(a). FDA also may require additional wording on other labeling components for the Rx new animal drug to be translated into the foreign language when necessary to ensure its safe and effective use.

(2) For approved or conditionally approved OTC new animal drugs other than new animal drugs for use in animal feeds, if a labeling component contains any section or wording translated into a foreign language, then the entire full product information must be translated into the foreign language and must comply with the format and content requirements in § 201.407(a). FDA also may require additional wording on other labeling components for the OTC new animal drug to be translated into the foreign language when necessary to ensure its safe and effective use.

(3) For approved or conditionally approved new animal drugs for use in animal feeds, if the labeling contains any section or wording translated into a foreign language, then all labeling must be translated into the foreign language and must comply with the format and content requirements in § 201.409.

(4) FDA may limit the number of languages into which labeling information is translated to ensure clarity of information and the safe and effective use of the new animal drug.

(j) For approved or conditionally approved new animal drugs distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is other than English, the predominant language may be substituted for English. Such new animal drugs may be exempt from paragraph (i) of this section.

§ 201.405 Content and format for prescription (Rx) new animal drug labeling.

This section describes specific content and format requirements for the labeling of approved or conditionally approved Rx new animal drugs. This section does not apply to new animal drugs approved or conditionally approved as veterinary feed directive (VFD) drugs. See § 201.409 for content and format requirements for the labeling of approved or conditionally approved new animal drugs for use in animal feeds that are subject to part 558 of this chapter, including VFD drugs. Omit labeling sections or subsections that do not apply to the Rx new animal drug. The final content of each applicable component and section of labeling is determined by FDA. In addition to the content and format requirements in this section, the labeling of approved or conditionally approved Rx new animal drugs must comply with other applicable requirements in this subpart.

(a) *Labeling providing full prescribing information.* All approved or conditionally approved Rx new animal drugs must provide full prescribing information as described in this paragraph. The package insert must include full prescribing information. If no package insert is provided, a secondary container is required, and its labeling must include full prescribing information as described in this paragraph. The following information, as applicable, must appear in the order listed on the labeling component providing full prescribing information. If full prescribing information is provided on the secondary container labeling, in accordance with section 201(k) of the Federal Food, Drug, and Cosmetic Act, the secondary container labeling may exclude any of the information described in this subsection that is required by paragraphs (b) or (c) of this section to appear on the label if such information is easily legible through the secondary container. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the labeling providing full prescribing information. Sections and subsections are not numbered on full prescribing information.

(1) *Drug product identification.* This section of full prescribing information must include:

(i) The proprietary name of the finished drug product;

(ii) The established name of the drug product;

(iii) The route(s) of administration, if not included as part of the established name of the drug product;

(iv) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(v) The established name and strength or concentration of each active ingredient, except that the strength or concentration may be excluded from full prescribing information provided on a package insert that applies to multiple strengths or concentrations;

(vi) The pharmacological class of the new animal drug, if required to facilitate the drug's safe and effective use; and

(vii) For controlled substances, the required controlled substance symbol, in accordance with part 1302 of this title designating the schedule for the drug substance.

(2) *Prescription statement.* This section of full prescribing information must include the following statement: ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian''.

(3) *Conditional approval statement.* All conditionally approved new animal drugs must include the following statement in this section of full prescribing information in accordance with section 571(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act: ''conditionally approved by FDA pending a full demonstration of effectiveness under application number [insert number]''. This statement must be prominent and conspicuous.

(4) *Boxed warnings.* All Rx new animal drugs with boxed warnings must include the boxed warning in this section of full prescribing information.

The box must contain, in upper case letters, the heading ''WARNING''. The contents of the box must briefly explain the risk and, if appropriate, refer to more detailed information in other sections of full prescribing information. The box, heading, and contents must be bolded.

(5) *Extralabel use prohibition statement.* An approved new animal drug that is prohibited from extralabel use as listed under § 530.41 of this chapter must include in this section of full prescribing information an extralabel use prohibition statement that begins with the phrase: ''Federal law prohibits the extralabel use of this drug . . .'' and concludes with a description of the prohibition as described in § 530.41 of this chapter.

(6) ''*Description*''. This section of full prescribing information must include:

(i) The proprietary name of the finished drug product;

(ii) The established name of the drug product;

(iii) The route(s) of administration, if not included as part of the established name of the drug product;

(iv) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(v) A description of the identifying characteristics of the dosage form, such as color, shape, coating, scoring, and imprinting;

(vi) The established name and strength or concentration of each active ingredient, including all available strengths or concentrations to which full prescribing information applies;

(vii) If applicable, a statement that the product is sterile; and

(viii) The established name of each inactive ingredient presented in decreasing order of predominance, by weight or concentration.

(A) If exemption from listing one or more inactive ingredients is granted, in accordance with § 201.411, to avoid disclosure of trade secret information, this section of full prescribing information must also state the following: ''Certain inactive ingredients are not listed to avoid disclosing trade secret information.''

(B) If exemption from listing one or more inactive ingredients is granted, in accordance with § 201.411, because their listing would be impracticable, this section of full prescribing information must also state the following: ''Certain inactive ingredients are not listed because their listing would be impracticable.''

(7) ''*Indications for Use*''. Include the following information in this section of full prescribing information in order:

(i) The approved or conditionally approved indication(s) and target animal(s) in the following format: ''For [indication(s)] in [target animal(s)]'';

(ii) A statement indicating that the new animal drug is approved or conditionally approved for use only under specific conditions, if applicable; and

(iii) A statement(s) indicating animals for which the new animal drug is not approved or conditionally approved, if FDA determines such a statement(s) is required for safety and/or effectiveness reasons.

(8) ''*Dosage and Administration*''. This section of full prescribing information must include for each indication and target animal:

(i) The statement, ''Always provide [additional labeling] with each prescription'' for Rx new animal drugs requiring additional labeling, in accordance with paragraph (a)(14) of this section, inserting the title of the additional labeling in the location indicated by the bracketed text;

(ii) The route(s) of administration, and specific site(s) of administration, if applicable;

(iii) The dose (or dose range);

(iv) The intervals between doses, if applicable;

(v) The duration of treatment;

(vi) The maximum volume per injection site, if required to facilitate the drug's safe and effective use;

(vii) Any modification of the information required in paragraphs (a)(8)(i) through (vi) of this section that is needed for special animal populations (*e.g.,* neonatal, reproducing, lactating, geriatric, or those with specific disease states); and

(viii) Other information regarding dosage and administration, if required to facilitate the drug's safe and effective use.

(9) ''*Contraindications*''. All Rx new animal drugs with contraindications must include the contraindications in this section of full prescribing information.

(10) ''*Warnings and Precautions*''. This section of full prescribing information is required for all approved or conditionally approved Rx new animal drugs. Include in the following order all applicable subsections, headings, and information:

(i) ''*Withdrawal Periods and Residue Warnings*'' *or* ''*Withdrawal Periods*''. This subsection of full prescribing information is required for all new animal drugs approved or conditionally approved for use in food-producing animals and must include all human food safety warnings, including milk discard times, withdrawal periods, and residue warning statements, as applicable. The order of the human food safety warnings in this subsection of full prescribing information must be as described in paragraphs (a)(10)(i)(B) through (G) of this section, as applicable.

(A) If there is a residue warning statement(s), this subsection of full prescribing information must be entitled ''Withdrawal Periods and Residue Warnings''. If there is no residue warning statement, this subsection of full prescribing information must be entitled ''Withdrawal Periods''. The title of this subsection and all information in this subsection of full prescribing information must be centered and placed entirely within compressed arrows, in accordance with § 201.404(g)(8). The compressed arrows must be black for package inserts or a color that clearly contrasts from background colors for other approved labeling.

(B) If the new animal drug is approved or conditionally approved for use in food-producing animals excluding female animals that produce milk for human consumption, include in this subsection of full prescribing information the withdrawal period(s) followed by any residue warning statements.

(C) If the new animal drug is approved or conditionally approved for use in food-producing animals excluding female animals that produce milk for human consumption and there is no withdrawal period, include in this subsection of full prescribing information the statement ''No withdrawal period is required when used according to labeling.'', followed by any residue warning statements.

(D) If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption, include in this subsection of full prescribing information the milk discard time(s), followed by the withdrawal period(s), followed by any residue warning statements.

(E) If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption and there is a milk discard time(s) but no withdrawal period, include in this subsection of full prescribing information the milk discard time(s), followed by the statement ''No withdrawal period is required when used according to labeling.'', followed by any residue warning statements.

(F) If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption and there is no

milk discard time but there is a withdrawal period(s), include in this subsection of full prescribing information the withdrawal period(s), followed by the statement ''No milk discard time is required when used according to labeling.'', followed by any residue warning statements.

(G) If the new animal drug is approved or conditionally approved for use in female animals that produce milk for human consumption and there is no milk discard time and no withdrawal period, include in this subsection of full prescribing information the statement ''No milk discard time and no withdrawal period is required when used according to labeling.'', followed by any residue warning statements.

(ii) ''*User Safety Warnings*''. This subsection of full prescribing information is required for all new animal drugs and must include in the following order:

(A) ''Not for use in humans. Keep out of reach of children.''

(B) All additional user safety warnings listed in decreasing order of severity or frequency; and

(C) ''To obtain a Safety Data Sheet(s), contact [insert name of manufacturer] at [insert manufacturer's telephone number] or [insert manufacturer's website].''

(iii) ''*Animal Safety Warnings and Precautions*''. All target animal safety warnings that identify any serious adverse reaction or potential hazard to the target animal(s) associated with the use of the new animal drug and all precautions must be included in this subsection of full prescribing information. These items must be listed in decreasing order of severity or frequency.

(iv) ''*Environmental Warnings*''. All environmental warnings applicable to the new animal drug that are included in an approved or conditionally approved application must be provided in this subsection of full prescribing information.

(v) ''*Other Warnings*''. Any other required warnings must be included in this subsection of full prescribing information.

(11) ''*Adverse Reactions*''. Include in this section of full prescribing information the adverse reactions, as determined by FDA, that occur with use of the Rx new animal drug and with use of drugs in the same pharmacologically active and chemically related class, if applicable. Include information necessary to interpret the adverse reactions (*e.g.,* for field studies include total number of animals exposed, extent and nature of exposure). Within the following categories, as applicable, present the adverse reactions in decreasing order of severity or frequency.

(i) ''*Pre-approval experience*''. Include adverse reactions observed in laboratory or field studies in the target animal(s).

(ii) ''*Foreign market experience*''. If the drug product has been commercially marketed outside the United States, include information from foreign adverse drug experience reports known prior to U.S. approval.

(iii) ''*Post-approval experience*''. Include the adverse reactions identified from domestic and foreign adverse drug experience reports.

(12) ''*Contact Information*''. The following statements must be included in this section of full prescribing information: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report suspected adverse drug experiences, contact [insert name of business] at [insert business telephone number]. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Use as the name of the business the manufacturer, packer, or distributor identified in the ''Name and place of business'' section of full prescribing information according to paragraph (a)(22) of this section. If more than one business is identified in the ''Name and place of business'' section of full prescribing information, select the most appropriate to identify as the ''business'' in the ''Contact Information'' section of full prescribing information to provide additional information about the Rx new animal drug and to contact regarding suspected adverse drug experiences.

(13) ''*Information for Animal Owner*''. Any specific information that FDA determines is necessary for the animal owner or person treating the animal to use the Rx new animal drug safely and effectively must be included in this section of full prescribing information. If FDA requires additional labeling (*e.g.,* a client information sheet), a printed copy must be attached to, or accompany, the package insert or secondary container labeling if no package insert is provided.

(14) ''*Clinical Pharmacology*''. If required by FDA to facilitate the drug's safe and effective use, include a summary of the clinical pharmacology of the Rx new animal drug in the target animal(s) in this section of full prescribing information, including the following three subsections, as applicable:

(i) ''Mechanism of action'';

(ii) ''Pharmacodynamics''; and

(iii) ''Pharmacokinetics''.

(15) ''*Microbiology*''. This section of full prescribing information is required for all antimicrobial Rx new animal drugs and must include a description of microbiologic data associated with the studies used to support the effectiveness of the drug against the indicated pathogens. Microbiology data must be restricted to organisms named in the approved or conditionally approved indications. If *in vitro* data for antimicrobial new animal drugs are included in this section of full prescribing information that have not been correlated to clinical effectiveness, the data must be immediately preceded by the statement: ''The following *in vitro* data are available, but their clinical significance is unknown.''

(16) ''*Target Animal Safety*''. This section of full prescribing information must include a summary of the basis for the conclusion that the new animal drug is safe in the target animal(s) when used as approved or conditionally approved.

(17) ''*Effectiveness*''. This section of full prescribing information must include a summary of the basis for the conclusion that the new animal drug is effective in the target animal(s) when used as approved. For a conditionally approved new animal drug, include a summary of the basis for the reasonable expectation of effectiveness.

(18) ''*Net Contents*''. This section of full prescribing information must identify the contents of the secondary container. Exclude this section from package inserts.

(19) ''*How Supplied*''. This section of full prescribing information must include information on the available drug strengths, concentrations, and container sizes to which the labeling applies. Revise this section of full prescribing information if new strengths, concentrations, or container sizes are added.

(20) ''*Storage, Handling, and Disposal*''. This section of full prescribing information must include drug storage information. Also include any required handling and drug disposal information in this section.

(21) *NADA/ANADA approval statement.* In accordance with section 502(w)(3) of the Federal Food, Drug, and Cosmetic Act, approved new animal drugs must include the following statement in this section of full prescribing information: ''Approved by FDA under NADA # xxx–xxx''. Approved generic new animal drugs must include the following statement in

this section of full prescribing information: ''Approved by FDA under ANADA # xxx-xxx''. This statement must appear in this section of full prescribing information and:

(i) Appear on one straight line unless there is insufficient space, in which case the statement may appear on two straight lines;

(ii) Not be incorporated into a seal, stamp, logo or other graphic;

(iii) Be of consistent type size, color, and contrast and be of no greater prominence than the rest of the labeling text; and

(iv) Not obscure or otherwise render less conspicuous any word, statement, or other information required by FDA.

(22) *Name and place of business.* This section of full prescribing information must include the name and place of business of the manufacturer, packer, or distributor.

(23) ''*Lot Number and Expiration Date*''. This section is required when full prescribing information is provided on the secondary container labeling. This section must include the identifying lot or control number of the Rx new animal drug within the secondary container. This section must also include the expiration date of the Rx new animal drug within the secondary container, in accordance with § 201.17. Alternatively, this section must refer to the location on the secondary container labeling or secondary container where the lot or control number and expiration date are printed. In accordance with § 201.17, an expiration date may be excluded from the secondary container labeling or secondary container if the expiration date provided on the label or immediate container is easily legible through the secondary container.

(24) ''*Revision Date*''. This section of full prescribing information must include the date of the most recent revision of the component of labeling that provides full prescribing information, listing the month followed by the year.

(b) *Prescription new animal drug label (Rx label).* All approved or conditionally approved Rx new animal drugs must provide a label (Rx label). The following information, as applicable, must appear in the order listed on the Rx label. If there is insufficient space on the immediate container for a label to provide for all of the following information, then an Rx small label is required instead. The requirements for an Rx small label are provided in paragraph (c) of this section. Section headings and other text presented in quotations in this paragraph must appear verbatim on the Rx label. Sections are not numbered on the Rx label. For Rx labels with a front panel and one side or back panel, the information identified in paragraph (b)(1) of this section must be provided on the front panel in the order listed, and the information identified in paragraph (b)(2) of this section must be provided on the side or back panel in the order listed. If the Rx label consists of a single panel, the information identified in paragraph (b)(1) must be provided on the Rx label in the order listed followed by the information identified in paragraph (b)(2) in the order listed. For Rx labels with a front panel and multiple side and/or back panels, the information identified in paragraph (b)(1) must be provided on the Rx label in the order listed followed by the information identified in paragraph (b)(2) in the order listed, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information is presented. In all instances, the information specified in paragraphs (b)(2)(iii) and (iv) must appear on the same panel.

(1) *Front panel.* The following information must appear on the front panel of the Rx label in the order listed.

(i) *Drug product identification.* This section of the Rx label must include:

(A) The proprietary name of the finished drug product;

(B) The established name of the drug product;

(C) The route(s) of administration, if not included as part of the established name of the drug product;

(D) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(E) The established name and strength or concentration of each active ingredient;

(F) If applicable, a statement that the product is sterile;

(G) The pharmacological class of the new animal drug, if required to facilitate the drug's safe and effective use; and

(H) For controlled substances, the required controlled substance symbol, in accordance with part 1302 of this title designating the schedule for the drug substance.

(ii) *Prescription statement.* This section of the Rx label must include the following statement, in accordance with section 503(f)(4) of the Federal Food, Drug, and Cosmetic Act: ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(iii) *Conditional approval statement.* For conditionally approved new animal drugs, the requirements of paragraph (a)(3) of this section apply.

(iv) *Boxed warnings.* For Rx new animal drugs that have boxed warnings, the requirements of paragraph (a)(4) of this section apply.

(v) ''*Indications for Use*''. The requirements of paragraph (a)(7) of this section apply. However, if there is insufficient space on the Rx label for the complete ''Indications for Use'' section as specified in paragraph (a)(7), then include the statement required in paragraph (a)(7)(i) or, if there is insufficient space on the Rx label for the statement in paragraph (a)(7)(i), then include the statement, ''For [abbreviated indication(s)] in [target animal(s)]''. In either situation where there is insufficient space on the Rx label for the complete ''Indications for Use'' section as specified in paragraph (a)(7), the required statement must be followed by, ''See package insert for complete 'Indications for Use''' if full prescribing information is provided on a package insert, or ''See package labeling for complete 'Indications for Use''' if full prescribing information is provided on the secondary container labeling.

(vi) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of paragraph (a)(5) of this section apply.

(vii) ''*Withdrawal Periods and Residue Warnings*'' *or* ''*Withdrawal Periods*''. For new animal drugs approved or conditionally approved for use in food-producing animals, the requirements of paragraph (a)(10)(i) of this section apply. If there is insufficient space on the front panel of Rx labels consisting of only a front panel and one side or back panel for the information required in paragraph (a)(10)(i), this section must be provided on the side or back panel of the Rx label immediately following the full prescribing information statement specified in paragraph (b)(2)(i) of this section.

(viii) ''*Net Contents*''. This section of the Rx label must identify the contents of the immediate container, in accordance with § 201.5.

(ix) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of paragraph (a)(21) of this section apply.

(2) *Side or back panel.* The following information must appear on the side or back panel of the Rx label in the order listed.

(i) *Full prescribing information statement.* This section of the Rx label must include one of two statements. If full prescribing information is provided

on the package insert, the following statement must be used: ''Before using this drug, read package insert for full prescribing information.'' If full prescribing information is provided on the secondary container labeling, the following statement must be used: ''Before using this drug, read package labeling for full prescribing information.''

(ii) ''*Dosage and Administration*''. The requirements of paragraph (a)(8) of this section apply. If there is insufficient space on the Rx label for the complete requirements as specified in paragraph (a)(8) or if it is necessary for additional information provided in full prescribing information that is not provided on the Rx label to be read before administering the drug, FDA may allow this section to be excluded from the Rx label.

(iii) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the Rx label must provide the established name and strength or concentration of each active ingredient. If the Rx new animal drug contains one active ingredient, this section of the Rx label must be entitled ''Active Ingredient''. If the Rx new animal drug contains more than one active ingredient, this section of the Rx label must be entitled ''Active Ingredients.''

(iv) ''*Inactive Ingredients*''. The requirements of paragraph (a)(6)(viii) of this section apply.

(v) ''*Storage, Handling, and Disposal*''. The requirements of paragraph (a)(20) of this section apply.

(vi) *Name and place of business.* This section of the Rx label must include the name and place of business of the manufacturer, packer, or distributor, in accordance with section 502(b) of the Federal Food, Drug, and Cosmetic Act.

(vii) ''*Lot Number and Expiration Date*'' *or* ''*Lot Number*''. This section of the Rx label must include the identifying lot or control number of the Rx new animal drug within the immediate container. This section of the Rx label must also include the expiration date of the Rx new animal drug within the immediate container, in accordance with § 201.17. Alternatively, this section must refer to the location on the Rx label or immediate container where the lot or control number and expiration date are printed. In accordance with § 201.17, if the immediate container provides a single dose of the Rx new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, an expiration date is not required on the Rx label or immediate container. If an expiration date is not provided on the Rx label or immediate container per this provision, then this section of the Rx label must be entitled ''Lot Number.''

(viii) ''*Revision Date*''. This section of the Rx label must include the date of the most recent revision of the Rx label, listing the month followed by the year.

(c) *Prescription new animal drug small label (Rx small label).* The following information, as applicable, must appear in the order listed on the Rx small label. FDA will make the final determination as to whether an immediate container lacks sufficient space for the label to include all of the information required by paragraph (b) of this section, taking into consideration readability and legibility of the information. Section headings and other text presented in quotations in this paragraph must appear verbatim on the Rx small label. Sections are not numbered on the Rx small label.

(1) *Proprietary name.* This section of the Rx small label must provide the proprietary name of the finished drug product.

(2) *Established name.* This section of the Rx small label must provide the established name of the drug product.

(3) *Active ingredient(s).* This section of the Rx small label must provide the established name and strength or concentration of each active ingredient.

(4) *Controlled substance symbol.* For controlled substances, this section of the Rx small label must include the required controlled substance symbol, in accordance with part 1302 of this title designating the schedule for the drug substance.

(5) *Prescription statement.* This section of the Rx small label must include the following: ''Rx Animal Use''.

(6) *Target animals.* This section of the Rx small label must include the statement: ''For [target animal(s)] only''.

(7) *Full prescribing information statement.* This section of the Rx small label must include one of two statements. If full prescribing information is provided on the package insert, the following statement must be used: ''Read package insert for full prescribing information.'' If full prescribing information is provided on the secondary container labeling, the following statement must be used: ''Read package labeling for full prescribing information.''

(8) ''*Net Contents*''. This section of the Rx small label must identify the contents of the immediate container, in accordance with § 201.51.

(9) *Name and place of business.* This section of the Rx small label must include the name and place of business of the manufacturer, packer, or distributor, in accordance with section 502(b) of the Federal Food, Drug, and Cosmetic Act.

(10) ''*Lot, Exp. and Storage*'' *or* ''*Lot and Storage*''. This section of the Rx small label must include the identifying lot or control number of the Rx new animal drug within the immediate container. This section of the Rx small label must also include the expiration date of the Rx new animal drug within the immediate container, in accordance with § 201.17. Drug storage information for the Rx new animal drug must also be included in this section of the Rx small label. In accordance with § 201.17, if the immediate container provides a single dose of the Rx new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, an expiration date is not required on the Rx small label or immediate container. If an expiration date is not provided on the Rx small label or immediate container per this provision, then this section of the Rx small label must be entitled ''Lot and Storage.''

(11) ''*Revision Date*''. This section of the Rx small label must include the date of the most recent revision of the Rx small label, listing the month followed by the year.

(d) *Labeling for secondary containers for Rx new animal drugs that include a package insert (Rx secondary container labeling).* If a secondary container is provided for an approved or conditionally approved Rx new animal drug and the Rx new animal drug includes a package insert, the following information, as applicable, must appear in the order listed on the secondary container labeling (Rx secondary container labeling). In accordance with section 201(k) of the Federal Food, Drug, and Cosmetic Act, the Rx secondary container labeling may exclude any of the information described in this subsection that is required by paragraphs (b) or (c) of this section to appear on the label if such information is easily legible through the Rx secondary container. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the Rx secondary container labeling. Sections and subsections are not numbered on the Rx secondary container labeling. For Rx secondary container labeling with a front panel and one side or back panel, the information identified in paragraph (d)(1) of this section must be provided on the front panel in the order listed, and the information identified in

paragraph (d)(2) of this section must be provided on the side or back panel in the order listed. For Rx secondary container labeling with a front panel and multiple side and/or back panels, the information identified in paragraph (d)(1) must be provided on the Rx secondary container labeling in the order listed followed by the information identified in paragraph (d)(2) in the order listed, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information is presented. In all instances, the information specified in paragraphs (d)(2)(v) and (vi) of this section must appear on the same panel.

(1) *Front panel.* The following information must appear on the front panel of the Rx secondary container labeling in the order listed.

(i) *Drug product identification.* This section of the Rx secondary container labeling must include:

(A) The proprietary name of the finished drug product;

(B) The established name of the drug product;

(C) The route(s) of administration, if not included as part of the established name of the drug product;

(D) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(E) The established name and strength or concentration of each active ingredient;

(F) If applicable, a statement that the product is sterile;

(G) The pharmacological class of the new animal drug, if required to facilitate the drug's safe and effective use; and

(H) For controlled substances, the required controlled substance symbol, in accordance with part 1302 of this title designating the schedule for the drug substance.

(ii) *Prescription statement.* The requirements of paragraph (a)(2) of this section apply.

(iii) *Conditional approval statement.* The requirements of paragraph (a)(3) of this section apply.

(iv) *Boxed warnings.* The requirements of paragraph (a)(4) of this section apply.

(v) ''*Indications for Use*''. The requirements of paragraph (a)(7) of this section apply.

(vi) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of paragraph (a)(5) of this section apply.

(vii) ''*Net Contents*''. This section of the Rx secondary container labeling must identify the contents of the secondary container.

(viii) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of paragraph (a)(21) of this section apply.

(2) *Side or back panel.* The following information must appear on the side or back panel of the Rx secondary container labeling in the order listed.

(i) *Full prescribing information statement.* This section of the Rx secondary container labeling must include the following statement: ''Before using this drug, read package insert for full prescribing information.''

(ii) ''*Dosage and Administration*''. The requirements of paragraph (a)(8) of this section apply.

(iii) ''*Contraindications*''. The requirements of paragraph (a)(9) of this section apply.

(iv) ''*Warnings and Precautions*''. The requirements of paragraph (a)(10) of this section apply.

(v) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. The requirements of paragraph (b)(2)(iii) of this section apply.

(vi) ''*Inactive Ingredients*''. The requirements of paragraph (a)(6)(viii) of this section apply.

(vii) ''*Storage, Handling, and Disposal*''. The requirements of paragraph (a)(20) of this section apply.

(viii) *Name and place of business.* The requirements of paragraph (a)(22) of this section apply.

(ix) ''*Lot Number and Expiration Date*''. This section of the Rx secondary container labeling must include the identifying lot or control number of the Rx new animal drug within the secondary container. This section of the Rx secondary container labeling must also include the expiration date of the Rx new animal drug within the secondary container, in accordance with § 201.17. Alternatively, this section must refer to the location on the Rx secondary container labeling or secondary container where the lot or control number and expiration date are printed. In accordance with § 201.17, an expiration date may be excluded from the Rx secondary container labeling or secondary container if the expiration date provided on the Rx label, Rx small label, or immediate container is easily legible through the secondary container.

(x) ''*Revision Date*''. This section of the Rx secondary container labeling must include the date of the most recent version of the Rx secondary container labeling, listing the month followed by the year.

(e) *Shipping labeling for Rx new animal drugs (Rx shipping labeling).* If shipping labeling is provided for an approved or conditionally approved Rx new animal drug (Rx shipping labeling), the following information, as applicable, must appear in the order listed on the Rx shipping labeling. Section headings and other text presented in quotations in this paragraph must appear verbatim on the Rx shipping labeling. Sections are not numbered on the Rx shipping labeling.

(1) *Proprietary name.* This section of the Rx shipping labeling must provide the proprietary name of the finished drug product, unless the Rx new animal drug is a controlled substance.

(2) *Established name.* This section of the Rx shipping labeling must provide the established name of the drug product, unless the Rx new animal drug is a controlled substance.

(3) *Active ingredient(s).* This section of the Rx shipping labeling must provide the established name and strength or concentration of each active ingredient, unless the Rx new animal drug is a controlled substance.

(4) *Conditional approval statement.* The requirements of paragraph (a)(3) of this section apply, unless the Rx new animal drug is a controlled substance.

(5) ''*Net Contents*''. This section of the Rx shipping labeling must identify the contents of the shipping carton.

(6) ''*Storage and Handling*''. This section of the Rx shipping labeling must include drug storage information. If required by FDA to facilitate the drug's safe and effective use, also include handling information.

(7) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of paragraph (a)(21) of this section apply, unless the Rx new animal drug is a controlled substance.

(8) *Name and place of business.* The requirements of paragraph (a)(22) of this section apply.

(9) ''*Lot Number and Expiration Date*''. This section of the Rx shipping labeling must include the identifying lot or control number(s) and the expiration date(s) of the Rx new animal drug within the shipping carton.

(10) ''*Revision Date*''. This section of the Rx shipping labeling must include the date of the most recent revision of the Rx shipping labeling, listing the month followed by the year.

(f) *Other approved labeling for Rx new animal drugs (Rx other approved labeling).* If other approved labeling is provided for an approved or conditionally approved Rx new animal drug (Rx other approved labeling), such as labeling on display cartons and multi-unit cartons (excluding shipping

cartons), the following information, as applicable, must appear in the order listed on the Rx other approved labeling. Section headings and other text presented in quotations in this paragraph must appear verbatim on the Rx other approved labeling. Sections are not numbered on the Rx other approved labeling.

(1) *Proprietary name.* This section of the Rx other approved labeling must provide the proprietary name of the finished drug product.

(2) *Established Name.* This section of the Rx other approved labeling must provide the established name of the drug product.

(3) *Active ingredient(s).* This section of the Rx other approved labeling must provide the established name and strength or concentration of each active ingredient.

(4) *Controlled substance symbol.* For controlled substances, this section of the Rx other approved labeling must include the required controlled substance symbol, in accordance with part 1302 of this title designating the schedule for the drug substance.

(5) *Prescription statement.* The requirements of paragraph (a)(2) of this section apply.

(6) *Conditional approval statement.* The requirements of paragraph (a)(3) of this section apply.

(7) *Boxed warnings.* The requirements of paragraph (a)(4) of this section apply.

(8) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of paragraph (a)(5) of this section apply.

(9) ''*Net Contents*''. This section of the Rx other approved labeling must identify the contents of the container to which the Rx other approved labeling applies.

(10) ''*Storage, Handling, and Disposal*''. The requirements of paragraph (a)(20) of this section apply.

(11) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of paragraph (a)(21) of this section apply.

(12) *Name and place of business.* The requirements of paragraph (a)(22) of this section apply.

(13) ''*Lot Number and Expiration Date*''. This section of the Rx other approved labeling must include the identifying lot or control number of the Rx new animal drug within the container to which the Rx other approved labeling applies. This section of the Rx other approved labeling must also include the expiration date of the Rx new animal drug within the container to which the Rx other approved labeling applies. In accordance with § 201.17, an expiration date may be excluded from the Rx other approved labeling if the expiration date provided on containers within or their labeling is easily legible through the container to which the Rx other approved labeling applies.

(14) ''*Revision Date*''. This section of the Rx other approved labeling must include the date of the most recent revision of the Rx other approved labeling, listing the month followed by the year.

§ 201.407 Content and format for over-the-counter (OTC) new animal drug labeling.

This section describes specific content and format requirements for the labeling of approved or conditionally approved OTC new animal drugs other than those for use in animal feeds that are subject to part 558 of this chapter. See § 201.409 for content and format requirements for the labeling of approved or conditionally approved new animal drugs for use in animal feeds that are subject to part 558 of this chapter. Omit labeling sections or subsections that do not apply to the OTC new animal drug. The final content of each applicable component and section of labeling is determined by FDA. In addition to the content and format requirements in this section, the labeling of approved or conditionally approved OTC new animal drugs must comply with other applicable requirements in this subpart.

(a) *Labeling providing full product information.* All approved or conditionally approved OTC new animal drugs must provide full product information as described in this paragraph. The package insert must include full product information. If no package insert is provided, the secondary container labeling must include full product information as described in this paragraph. If neither a package insert nor a secondary container is provided, the label must include full product information as described in this paragraph. The following information, as applicable, must appear in the order listed on the labeling component providing full product information. If full product information is provided on the secondary container labeling, in accordance with section 201(k) of the Federal Food, Drug, and Cosmetic Act, the secondary container labeling may exclude any of the information described in this subsection that is required by paragraphs (b) or (c) of this section to appear on the label if such information is easily legible through the secondary container. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the labeling providing full product information. Sections and subsections are not numbered on full product information.

(1) *Drug product identification.* This section of full product information must include:

(i) The proprietary name of the finished drug product;

(ii) The established name of the drug product;

(iii) The route(s) of administration, if not included as part of the established name of the drug product;

(iv) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(v) The established name and strength or concentration of each active ingredient, except that the strength or concentration may be excluded from full product information provided on a package insert that applies to multiple strengths or concentrations; and

(vi) The pharmacological class of the new animal drug, if required to facilitate the drug's safe and effective use.

(2) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(3) ''*Uses*''. Include the following information in this section of full product information in order:

(i) The approved or conditionally approved indication(s) and target animal(s) in the following format: ''For [indication(s)] in [target animal(s)]'';

(ii) A statement indicating that the new animal drug is approved or conditionally approved for use only under specific conditions, if applicable;

(iii) A statement describing the relative effectiveness of doses within the approved range of doses, if required by FDA to facilitate the drug's safe and effective use; and

(iv) A statement(s) indicating animals for which the new animal drug is not approved or conditionally approved, if FDA determines such a statement(s) is required for safety and/or effectiveness reasons.

(4) *Extralabel use statement.* This section of full product information must include the following extralabel use statement: ''It is a violation of Federal law to use this drug product other than as directed in the labeling or as directed by your veterinarian.''

(5) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of § 201.405(a)(5) apply.

(6) ''*Description*''. This section of full product information must include:

(i) The proprietary name of the finished drug product;

(ii) The established name of the drug product;

(iii) The route(s) of administration, if not included as part of the established name of the drug product;

(iv) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(v) A description of the identifying characteristics of the dosage form, such as color, shape, coating, scoring, and imprinting;

(vi) The established name and strength or concentration of each active ingredient, including all available strengths or concentrations to which full product information applies;

(vii) If applicable, a statement that the product is sterile; and

(viii) When inactive ingredients are provided on full product information, the requirements of § 201.405(a)(6)(viii) apply.

(7) ''*Warnings*''. This section of full product information is required for all approved or conditionally approved new animal drugs. Include in the following order all applicable subsections, headings, and information:

(i) ''*Withdrawal Periods and Residue Warnings*'' *or* ''*Withdrawal Periods*''. The requirements of § 201.405(a)(10)(i) apply.

(ii) ''*User Safety Warnings*''. The requirements of § 201.405(a)(10)(ii) apply.

(iii) ''*Animal Safety Warnings*''. All contraindications, target animal safety warnings that identify any serious adverse reaction or potential hazard to the target animal(s) associated with the use of the new animal drug, adverse reactions, and post-approval adverse drug experiences must be included in this subsection of full product information. These items must be listed in decreasing order of severity or frequency.

(iv) ''*Environmental Warnings*''. The requirements of § 201.405(a)(10)(iv) apply.

(v) ''*Other Warnings*''. The requirements of § 201.405(a)(10)(v) apply.

(8) ''*Additional Recommendations*''. This section of full product information must include all precautions.

(9) ''*Other Effects You May Notice*''. This section of full product information must include all statements required by FDA that identify any effects of the OTC new animal drug on the target animal(s) that are not considered contraindications, target animal safety warnings, adverse reactions, or post-approval adverse drug experiences.

(10) ''*Directions*''. This section of full product information must include for each indication and target animal:

(i) The route(s) of administration, and specific site(s) of administration, if applicable;

(ii) The dose (or dose range);

(iii) The intervals between doses, if applicable;

(iv) The duration of treatment;

(v) The maximum volume per injection site, if required to facilitate the drug's safe and effective use; and

(vi) Other information regarding administration, if required by FDA to facilitate the drug's safe and effective use.

(11) ''*Net Contents*''. This section of full product information, when presented on the label or the secondary container labeling, must identify the contents of the immediate container, in accordance with § 201.62, or the secondary container, respectively. Exclude this section from package inserts.

(12) ''*How Supplied*''. The requirements of § 201.405(a)(19) apply.

(13) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(14) ''*Questions/Comments?*''. The following statements must be included in this section of full product information: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report side effects, contact [insert name of business] at [insert business telephone number]. For additional information about reporting side effects for animal drugs, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Use as the name of the business the manufacturer, packer, or distributor identified in the ''Name and place of business'' section of full product information according to paragraph (a)(16) of this section. If more than one business is identified in the ''Name and place of business'' section of full product information, select the most appropriate to identify as the ''business'' in the ''Questions/Comments?'' section of full product information to provide additional information about the OTC new animal drug and to contact regarding suspected adverse drug experiences.

(15) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(16) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(17) ''*Lot Number and Expiration Date*''. This section is required when full product information is provided on the secondary container labeling or the label. This section must include the identifying lot or control number of the OTC new animal drug within the secondary container or immediate container. This section must also include the expiration date of the OTC new animal drug within the secondary container or immediate container, in accordance with § 201.17. Alternatively, this section must refer to the location on the secondary container labeling, secondary container, label, or immediate container where the lot or control number and expiration date are printed. If full product information is provided on the secondary container labeling, in accordance with § 201.17, an expiration date may be excluded from the secondary container labeling or secondary container if the expiration date provided on the label or immediate container is easily legible through the secondary container.

(18) ''*Revision Date*''. This section of full product information must include the date of the most recent revision of the component of labeling that provides full product information, listing the month followed by the year.

(b) *OTC new animal drug label not providing full product information (OTC label).* All approved or conditionally approved OTC new animal drugs must provide a label. If a package insert or secondary container labeling with full product information is provided for an approved or conditionally approved OTC new animal drug and the label does not provide full product information in accordance with paragraph (a) of this section, the following information, as applicable, must appear in the order listed on the label for approved or conditionally approved OTC new animal drugs (OTC label). If there is insufficient space on the immediate container for a label to provide for all of the following information, then an OTC small label is required instead. The requirements for an OTC small label are provided in paragraph (c) of this section. Section headings and other text presented in quotations in this paragraph must appear verbatim on the OTC label. Sections are not numbered on the OTC label. For OTC labels with a front panel and one side or back panel, the information identified in paragraph (b)(1) of this section must be provided on the front panel in the order listed,

and the information identified in paragraph (b)(2) of this section must be provided on the side or back panel in the order listed. If the OTC label consists of a single panel, the information identified in paragraph (b)(1) of this section must be provided on the OTC label in the order listed followed by the information identified in paragraph (b)(2) in the order listed. For OTC labels with a front panel and multiple side and/or back panels, the information identified in paragraph (b)(1) must be provided on the OTC label in the order listed followed by the information identified in paragraph (b)(2) in the order listed, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information is presented. In all instances, the information specified in paragraphs (b)(2)(iii) and (iv) of this section must appear on the same panel.

(1) *Front panel.* The following information must appear on the front panel of the OTC label in the order listed.

(i) *Drug product identification.* This section of the OTC label must include:

(A) The proprietary name of the finished drug product;

(B) The established name of the drug product;

(C) The route(s) of administration, if not included as part of the established name of the drug product;

(D) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(E) The established name and strength or concentration of each active ingredient;

(F) If applicable, a statement that the product is sterile; and

(G) The pharmacological class of the new animal drug, if required to facilitate the drug's safe and effective use.

(ii) *Conditional approval statement.* For conditionally approved new animal drugs, the requirements of § 201.405(a)(3) apply.

(iii) ''*Uses*''. The requirements of paragraph (a)(3) of this section apply. However, if there is insufficient space on the OTC label for the complete ''Uses'' section as specified in paragraph (a)(3), then include the statement required in paragraph (a)(3)(i) or, if there is insufficient space on the OTC label for the statement in paragraph (a)(3)(i), then include the statement, ''For [abbreviated indication(s)] in [target animal(s)]''). In either situation where there is insufficient space on the OTC label for the complete ''Uses'' section as specified in paragraph (a)(3), the required statement must be followed by, ''See package insert for complete 'Uses' '' if full product information is provided on a package insert, or ''See package labeling for complete 'Uses' '' if full product information is provided on the secondary container labeling.

(iv) *Extralabel use statement.* The requirements of paragraph (a)(4) of this section apply.

(v) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of § 201.405(a)(5) apply.

(vi) ''*Withdrawal Periods and Residue Warnings*'' *or* ''*Withdrawal Periods*''. For new animal drugs approved or conditionally approved for use in food-producing animals, the requirements of § 201.405(a)(10)(i) apply. If there is insufficient space on the front panel of OTC labels consisting of only a front panel and one side or back panel for the information required in § 201.405(a)(10)(i), this section must be provided on the side or back panel of the OTC label immediately following the complete product information statement specified in paragraph (b)(2)(i) of this section.

(vii) ''*Net Contents*''. This section of the OTC label must identify the contents of the immediate container, in accordance with § 201.62.

(viii) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(2) *Side or back panel.* The following information must appear on the side or back panel of the OTC label in the order listed.

(i) *Complete product information statement.* This section of the OTC label must include one of two statements. If full product information is provided on the package insert, the following statement must be used: ''Before using this drug, read package insert for complete product information.'' If full product information is provided on the secondary container labeling, the following statement must be used: ''Before using this drug, read package labeling for complete product information.''

(ii) ''*Directions*''. The requirements of paragraph (a)(10) of this section apply. If there is insufficient space on the OTC label for complete requirements as specified in paragraph (a)(10) of this section or if it is necessary for additional information provided in full product information that is not provided on the OTC label to be read before administering the drug, FDA may allow this section to be excluded from the OTC label.

(iii) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the OTC label must provide the established name and strength or concentration of each active ingredient. If the OTC new animal drug contains one active ingredient, this section of the OTC label must be entitled ''Active Ingredient''. If the OTC new animal drug contains more than one active ingredient, this section of the OTC label must be entitled ''Active Ingredients.''

(iv) ''*Inactive Ingredients*''. When inactive ingredients are provided on the OTC label, the requirements of § 201.405(a)(6)(viii) apply.

(v) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(vi) *Name and place of business.* This section of the OTC label must include the name and place of business of the manufacturer, packer, or distributor, in accordance with section 502(b) of the Federal Food, Drug, and Cosmetic Act.

(vii) ''*Lot Number and Expiration Date*'' *or* ''*Lot Number*''. This section of the OTC label must include the identifying lot or control number of the OTC new animal drug within the immediate container. This section of the OTC label must also include the expiration date of the OTC new animal drug within the immediate container, in accordance with § 201.17. Alternatively, this section must refer to the location on the OTC label or immediate container where the lot or control number and expiration date are printed. In accordance with § 201.17, if the immediate container provides a single dose of the OTC new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, an expiration date is not required on the OTC label or immediate container. If an expiration date is not provided on the OTC label or immediate container per this provision, then this section of the OTC label must be titled ''Lot Number.''

(viii) ''*Revision Date*''. This section of the OTC label must include the date of the most recent revision of the OTC label, listing the month followed by the year.

(c) *OTC new animal drug small label (OTC small label).* The following information must appear in the order listed on the OTC small label. FDA will make the final determination as to whether an immediate container lacks sufficient space for the label to include all of the information required by paragraph (b) of this section, taking into consideration readability and legibility

of the information. Section headings and other text presented in quotations in this paragraph must appear verbatim on the OTC small label. Sections are not numbered on the OTC small label.

(1) *Proprietary name.* This section of the OTC small label must provide the proprietary name of the finished drug product.

(2) *Established name.* This section of the OTC small label must provide the established name of the drug product.

(3) *Active ingredient(s).* This section of the OTC small label must provide the established name and strength or concentration of each active ingredient.

(4) *Target animals.* This section of the OTC small label must include the statement: ''For [target animal(s)] only.''

(5) *Complete product information statement.* This section of the OTC small label must include one of two statements. If full product information is provided on the package insert, the following statement must be used: ''Read package insert for complete product information.'' If full product information is provided on the secondary container labeling, the following statement must be used: ''Read package labeling for complete product information.''

(6) ''*Net Contents*''. This section of the OTC small label must identify the contents of the immediate container, in accordance with § 201.62.

(7) *Name and place of business.* This section of the OTC small label must include the name and place of business of the manufacturer, packer, or distributor, in accordance with section 502(b) of the Federal Food, Drug, and Cosmetic Act.

(8) ''*Lot, Exp. and Storage*'' *or* ''*Lot and Storage*''. This section of the OTC small label must include the identifying lot or control number of the OTC new animal drug within the immediate container. This section of the OTC small label must also include the expiration date of the OTC new animal drugs within the immediate container, in accordance with § 201.17. Drug storage information for the OTC new animal drug must also be included in this section of the OTC small label. In accordance with § 201.17, if the immediate container provides a single dose of the OTC new animal drug and is packaged individually in a secondary container that provides an expiration date on the secondary container labeling or secondary container, an expiration date is not required on the OTC small label or immediate container. If an expiration date is not provided on the OTC small label or immediate container per this provision, then this section of the OTC small label must be entitled ''Lot and Storage.''

(9) ''*Revision Date*''. This section of the OTC small label must include the date of the most recent revision of the OTC small label, listing the month followed by the year.

(d) *Labeling for secondary containers for OTC new animal drugs that include a package insert (OTC secondary container labeling).* If a secondary container is provided for an approved or conditionally approved OTC new animal drug and the OTC new animal drug includes a package insert, the following information, as applicable, must appear in the order listed on the secondary container labeling (OTC secondary container labeling). In accordance with section 201(k) of the Federal Food, Drug, and Cosmetic Act, the OTC secondary container labeling may exclude any of the information described in this subsection that is required by paragraphs (b) or (c) of this section to appear on the label if such information is easily legible through the OTC secondary container. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the OTC secondary container labeling. Sections and subsections are not numbered on the OTC secondary container labeling. For OTC secondary container labeling with a front panel and one side or back panel, the information identified in paragraph (d)(1) of this section must be provided on the front panel in the order listed, and the information identified in paragraph (d)(2) of this section must be provided on the side or back panel in the order listed. For OTC secondary container labeling with a front panel and multiple side and/or back panels, the information identified in paragraph (d)(1) of this section must be provided on the OTC secondary container labeling in the order listed followed by the information identified in paragraph (d)(2) of this section in the order listed, starting on the front panel, continuing on the panel immediately to the right of the front panel, and continuing to fill the panels to the right until all of the information is presented. In all instances, the information specified in paragraphs (d)(2)(iv) and (v) of this section must appear on the same panel.

(1) *Front panel.* The following information must appear on the front panel of the OTC secondary container labeling in the order listed.

(i) *Drug product identification.* This section of the OTC secondary container labeling must include:

(A) The proprietary name of the finished drug product;

(B) The established name of the drug product;

(C) The route(s) of administration, if not included as part of the established name of the drug product;

(D) The dosage form of the finished drug product, if not included as part of the established name of the drug product;

(E) The established name and strength or concentration of each active ingredient;

(F) If applicable, a statement that the product is sterile; and

(G) The pharmacological class of the new animal drug, if required to facilitate the drug's safe and effective use.

(ii) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(iii) ''*Uses*''. The requirements of paragraph (a)(3) of this section apply.

(iv) *Extralabel use statement.* The requirements of paragraph (a)(4) of this section apply.

(v) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of § 201.405(a)(5) apply.

(vi) ''*Net Contents*''. This section of the OTC secondary container labeling must identify the contents of the secondary container.

(vii) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(2) *Side or back panel.* The following information must appear on the side or back panel of the OTC secondary container labeling in the order listed.

(i) *Complete product information statement.* This section of the OTC secondary container labeling must include the following statement: ''Before using this drug, read package insert for complete product information.''

(ii) ''*Directions*''. The requirements of paragraph (a)(10) of this section apply.

(iii) ''*Warnings*''. The requirements of paragraph (a)(7) of this section apply.

(iv) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. The requirements of paragraph (b)(2)(iii) of this section apply.

(v) ''*Inactive Ingredients*''. When inactive ingredients are provided on the OTC secondary container labeling, the requirements of § 201.405(a)(6)(viii) apply.

(vi) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(vii) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(viii) ''*Lot Number and Expiration Date*''. This section of the OTC

secondary container labeling must include the identifying lot or control number of the OTC new animal drug within the secondary container. This section of the OTC secondary container labeling must also include the expiration date of the OTC new animal drug within the secondary container, in accordance with § 201.17. Alternatively, this section must refer to the location on the OTC secondary container labeling or secondary container where the lot or control number and expiration date are printed. In accordance with § 201.17, an expiration date may be excluded from the OTC secondary container labeling or secondary container if the expiration date provided on the OTC label, OTC small label, or immediate container is easily legible through the secondary container.

(ix) ''*Revision Date*''. This section of the OTC secondary container labeling must include the date of the most recent revision of the OTC secondary container labeling, listing the month followed by the year.

(e) *Shipping labeling for OTC new animal drugs (OTC shipping labeling).* If shipping labeling is provided for an approved or conditionally approved OTC new animal drug (OTC shipping labeling), the following information, as applicable, must appear in the order listed on the OTC shipping labeling. Section headings and other text presented in quotations in this paragraph must appear verbatim on the OTC shipping labeling. Sections are not numbered on the OTC shipping labeling.

(1) *Proprietary name.* This section of the OTC shipping labeling must provide the proprietary name of the finished drug product.

(2) *Established name.* This section of the OTC shipping labeling must provide the established name of the drug product.

(3) *Active ingredient(s).* This section of the OTC shipping labeling must provide the established name and strength or concentration of each active ingredient.

(4) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(5) ''*Net Contents*''. This section of the OTC shipping labeling must identify the contents of the shipping carton.

(6) ''*Storage and Handling*''. This section of the OTC shipping labeling must include drug storage information. If required by FDA to facilitate the drug's safe and effective use, also include handling information.

(7) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(8) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(9) ''*Lot Number and Expiration Date*''. This section of the OTC shipping labeling must include the identifying lot or control number(s) and the expiration date(s) of the OTC new animal drug within the shipping carton.

(10) ''*Revision Date*''. This section of the OTC shipping labeling must include the date of the most recent revision of OTC shipping labeling, listing the month followed by the year.

(f) *Other approved labeling for OTC new animal drugs (OTC other approved labeling).* If other approved labeling is provided for an approved or conditionally approved OTC new animal drug (OTC other approved labeling), such as labeling on display cartons and multi-unit cartons (excluding shipping cartons), the following information, as applicable, must appear in the order listed on the OTC other approved labeling. Section headings and other text presented in quotations in this paragraph must appear verbatim on the OTC other approved labeling. Sections are not numbered on the OTC other approved labeling.

(1) *Proprietary name.* This section of the OTC other approved labeling must provide the proprietary name of the finished drug product.

(2) *Established name.* This section of the OTC other approved labeling must provide the established name of the drug product.

(3) *Active ingredient(s).* This section of the OTC other approved labeling must provide the established name and strength or concentration of each active ingredient.

(4) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(5) *Extralabel use statement.* The requirements of paragraph (a)(4) of this section apply.

(6) *Extralabel use prohibition statement.* For approved new animal drugs prohibited from extralabel use as listed under § 530.41 of this chapter, the requirements of § 201.405(a)(5) apply.

(7) ''*Net Contents*''. This section of the OTC other approved labeling must identify the contents of the container to which the OTC other approved labeling applies.

(8) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(9) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(10) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(11) ''*Lot Number and Expiration Date*''. This section of the OTC other approved labeling must include the identifying lot or control number of the OTC new animal drug within the container to which the OTC other approved labeling applies. This section of the OTC other approved labeling must also include the expiration date of the OTC new animal drug within the container to which the OTC other approved labeling applies. In accordance with § 201.17, an expiration date may be excluded from the OTC other approved labeling if the expiration date on containers within or their labeling is easily legible through the container to which the OTC other approved labeling applies.

(12) ''*Revision Date*''. This section of the OTC other approved labeling must include the date of the most recent revision of the OTC other approved labeling, listing the month followed by the year.

§ 201.409 Content and format of labeling for new animal drugs for use in animal feeds.

This section describes specific content and format requirements for the labeling of approved or conditionally approved new animal drugs for use in animal feeds and that are subject to part 558 of this chapter, including VFD drugs. Omit labeling sections or subsections that do not apply to the new animal drug for use in animal feeds. The final content of each applicable component and section of labeling is determined by FDA. In addition to the content and format requirements in this section, the labeling of approved or conditionally approved new animal drugs for use in animal feeds and that are subject to part 558 of this chapter must comply with other applicable requirements in this subpart.

(a) *Type A medicated article label.* All approved or conditionally approved Type A medicated articles must provide a Type A medicated article label as described in this paragraph. The following information, as applicable, must appear in the order listed on the Type A medicated article label. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the Type A medicated article label. Sections and subsections are not numbered on the Type A medicated article label.

(1) *Type A medicated article identification.* This section of the Type

A medicated article label must include in order:

(i) The proprietary name of the Type A medicated article;

(ii) The established name of the Type A medicated article; and

(iii) The phrase ''Type A medicated article'' or ''Type A liquid medicated article,'' as applicable, if not included as part of the established name of the Type A medicated article.

(2) *VFD cautionary statement.* For VFD drugs, this section of the Type A medicated article label must prominently and conspicuously display the cautionary statement, in accordance with § 558.6(a)(6) of this chapter.

(3) *Manufacturing statement.* This section of the Type A medicated article label must include the statement: ''For further manufacturing only.''

(4) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(5) ''*Indications for Use*''. The requirements of § 201.407(a)(3) apply.

(6) *Extralabel use statement.* This section of the Type A medicated article label must include the following extralabel use statement: ''It is a violation of Federal law to use other than as directed in the labeling.''

(7) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the Type A medicated article label must provide the established name and concentration of each active ingredient in the Type A medicated article. If the Type A medicated article contains one active ingredient, this section of the Type A medicated article label must be entitled ''Active Ingredient.'' If the Type A medicated article contains more than one active ingredient, this section of the Type A medicated article label must be entitled ''Active Ingredients.''

(8) ''*Inactive Ingredients*''. When inactive ingredients are provided on the Type A medicated article label, the requirements of § 201.405(a)(6)(viii) apply.

(9) ''*Directions*''. This section of the Type A medicated article label must include the following three subsections in order:

(i) ''*Approved Concentration(s) of [Active Ingredient or Active Moiety] in Type C Medicated Feeds*''. This subsection of the Type A medicated article label must provide the approved concentration(s) of each active ingredient in Type C medicated feeds to be manufactured from the Type A medicated article for each approved or conditionally approved indications for use. If an active ingredient is a salt or other noncovalent derivative and its concentration(s) in paragraph (a)(7) of this section is expressed based on the active moiety, the approved concentration(s) in the Type C medicated feeds must be expressed based on the active moiety, and the title of this subsection must include the name of the active moiety instead of the active ingredient.

(ii) ''*Mixing Directions*''. This subsection of the Type A medicated article label must provide the approved mixing directions for the manufacture of approved medicated feeds from this Type A medicated article for each approved or conditionally approved indications for use, including an intermediate mixing step (*i.e.,* preblend step) if required.

(iii) ''*Feeding Directions*''. This subsection of the Type A medicated article label must provide the approved feeding directions for each approved or conditionally approved indications for use for Type C medicated feeds manufactured from this Type A medicated article.

(10) ''*Warnings*''. This section of the Type A medicated article label is required for all Type A medicated articles. Include in the following order all applicable subsections, headings, and information:

(i) ''*Withdrawal Periods and Residue Warnings*'' *or* ''*Withdrawal Periods*''. The requirements of § 201.405(a)(10)(i) apply.

(ii) ''*User Safety Warnings*''. The requirements of § 201.405(a)(10)(ii) apply.

(iii) ''*Animal Safety Warnings*''. The requirements of § 201.407(a)(7)(iii) apply.

(iv) ''*Environmental Warnings*''. The requirements of § 201.405(a)(10)(iv) apply.

(v) ''*Other Warnings*''. The requirements of § 201.405(a)(10)(v) apply.

(11) ''*Additional Recommendations*''. The requirements of § 201.407(a)(8) apply.

(12) ''*Other Effects You May Notice*''. The requirements of § 201.407(a)(9) apply.

(13) ''*Net Weight*''. This section of the Type A medicated article label must list the net weight of the Type A medicated article in the immediate container.

(14) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(15) ''*Questions/Comments?*''. The following statements must be included in this section of the Type A medicated article label: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. To report side effects, contact [insert name of business] at [insert business telephone number]. For additional information about reporting side effects for animal drugs, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Use as the name of the business the manufacturer, packer, or distributor identified in the ''Name and place of business'' section of the Type A medicated article label according to paragraph (a)(17) of this section. If more than one business is identified in the ''Name and place of business'' section of the Type A medicated article label, select the most appropriate to identify as the ''business'' in the ''Questions/Comments?'' section of the Type A medicated article label to provide additional information about the Type A medicated article and to contact regarding suspected adverse drug experiences.

(16) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(17) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(18) ''*Lot Number and Expiration Date*''. This section of the Type A medicated article label must include the identifying lot or control number of the Type A medicated article within the immediate container. In accordance with § 226.58(d) of this chapter, this section of the Type A medicated article label must also include the expiration date of the Type A medicated article within the immediate container. Alternatively, this section must refer to the location on the Type A medicated article label or immediate container where the lot or control number and expiration date are printed.

(19) ''*Revision Date*''. This section of the Type A medicated article label must include the date of the most recent revision of the Type A medicated article label, listing the month followed by the year.

(b) *Representative Type B medicated feed labeling.* The following information, as applicable, must appear in the order listed on the representative Type B medicated feed labeling. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the representative Type B medicated feed labeling. Sections and subsections are not numbered on the representative Type B medicated feed labeling.

(1) *Description of the Type B medicated feed.* This section of the representative Type B medicated feed labeling serves as a placeholder for the

proprietary name to be added by the feed manufacturer to the label of the final Type B medicated feed manufactured in accordance with the approved representative Type B labeling. The description of the Type B medicated feed must:

(i) Distinguish the Type B medicated feed from any other Type B medicated feeds approved or conditionally approved within the same application; and

(ii) Not include the proprietary name of a Type A medicated article.

(2) *Established name of the Type B medicated feed.* The established name of the Type B medicated feed must include in the following order:

(i) The active moiety or active ingredient of each new animal drug, as determined by FDA; and

(ii) One of the following statements, as applicable: ''Type B medicated feed'' or ''Type B liquid medicated feed''.

(3) *VFD cautionary statement.* The requirements of paragraph (a)(2) of this section apply.

(4) *Undiluted statement.* This section of the representative Type B medicated feed labeling must include the statement: ''Do Not Feed Undiluted.''

(5) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(6) ''*Indications for Use*''. The requirements of § 201.407(a)(3) apply. Include only the approved or conditionally approved indications for use for the specific Type B medicated feed to which the representative Type B medicated feed labeling applies.

(7) *Extralabel use statement.* The requirements of paragraph (a)(6) of this section apply.

(8) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the representative Type B medicated feed labeling must include the following information for the specific Type B medicated feed to which the representative Type B medicated feed labeling applies. If the Type B medicated feed contains one active ingredient, this section of the representative Type B medicated feed labeling must be entitled ''Active Ingredient.'' If the Type B medicated feed contains more than one active ingredient, this section of the representative Type B medicated feed labeling must be entitled ''Active Ingredients.''

(i) The established name of each active ingredient; and

(ii) The concentration or range of concentrations of each active ingredient as approved by FDA. If included as a range, the active ingredient concentrations must reference a footnote at the bottom of this page of the representative Type B labeling indicating that each final printed Type B medicated feed label must only include a single concentration of each active ingredient.

(9) ''*Guaranteed Analysis*''. This section of the representative Type B medicated feed labeling must provide for the nutritional content guarantees of the Type B medicated feed appropriate for the target animal(s) in addition to any other required specifications.

(10) ''*Ingredients*''. This section of the representative Type B medicated feed labeling must include the following:

(i) A statement that feed ingredients must be listed on each final printed Type B medicated feed label by their common or usual names in descending order of predominance by weight, in accordance with § 501.4(a) of this chapter, including their collective names where permitted, in accordance with § 501.4(b)(13) of this chapter; and

(ii) A statement that spices, flavorings, colorings, and chemical preservatives, if used, must be declared on each final printed Type B medicated feed label, in accordance with § 501.22 of this chapter.

(11) ''*Mixing Directions*''. This section of the representative Type B medicated feed labeling must provide the approved mixing directions for the manufacture of a Type C medicated feed(s) or another Type B medicated feed(s), as applicable, from the Type B medicated feed for which the representative Type B medicated feed labeling applies.

(12) ''*Warnings*''. The requirements of paragraph (a)(10) of this section apply. Include only the warnings for the specific Type B medicated feed to which the representative Type B medicated feed labeling applies.

(13) ''*Additional Recommendations*''. The requirements of § 201.407(a)(8) apply. Include only the precautions for the specific Type B medicated feed to which the representative Type B medicated feed labeling applies.

(14) ''*Other Effects You May Notice*''. The requirements of § 201.407(a)(9) apply. Include only statements of other effects for the specific Type B medicated feed to which the representative Type B medicated feed labeling applies.

(15) *Name and place of business.* This section of the representative Type B medicated feed labeling must provide for the name and place of business of the manufacturer, packer, or distributor of the final Type B medicated feed, in accordance with § 501.5 of this chapter.

(16) ''*Net Weight*''. This section of the representative Type B medicated feed labeling must provide for the statement on the final printed Type B medicated feed label of the net weight of the Type B medicated feed in the immediate container.

(17) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(18) ''*Questions/Comments?*''. The following statements must be included in this section of the representative Type B medicated feed labeling: ''Contact [name of business] at [business telephone number] or [business web address]. For additional information about reporting problems with medicated feeds, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' The information in the bracketed areas of the first statement are placeholders for the business of the manufacturer, packer, or distributor of the final Type B medicated feed to insert their name and contact information. The information in the bracketed areas of the second statement must be inserted by the sponsor of the new animal drug application.

(19) ''*Lot, Batch, or Control Number*''. This section of the representative Type B medicated feed labeling must provide for an identifying lot, batch, or control number on the final printed Type B medicated feed label.

(20) ''*Expiration Date*''. If an expiration date is required, in accordance with § 514.1(b)(5)(x) of this chapter, then this section of the representative Type B medicated feed labeling must provide for the expiration date to be printed on the final printed Type B medicated feed label. The approved expiration period must also be included in this section of the representative Type B medicated feed labeling.

(21) ''*Revision Date*''. This section of the representative Type B medicated feed labeling must include the date of the most recent revision of the representative Type B medicated feed labeling, listing the month followed by the year.

(c) *Representative Type C medicated feed labeling.* The following information, as applicable, must appear in the order listed on the representative Type C medicated feed labeling. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the representative Type C medicated feed labeling. Sections and subsections are not numbered on the representative Type C medicated feed labeling.

(1) *Description of the Type C medicated feed.* This section of the

representative Type C medicated feed labeling serves as a placeholder for the proprietary name to be added by the feed manufacturer to the label of the final Type C medicated feed manufactured in accordance with the approved representative Type C medicated feed labeling. The description of the Type C medicated feeds must:

(i) Distinguish the Type C medicated feed from any other Type C medicated feeds approved or conditionally approved within the same application; and

(ii) Not include the proprietary name of a Type A medicated article.

(2) *Established name of the Type C medicated feed.* The established name of the Type C medicated feed must include in the following order:

(i) The active moiety or active ingredient of each new animal drug, as determined by FDA; and

(ii) One of the following statements, as applicable: ''Type C medicated feed,'' ''Type C liquid medicated feed,'' ''Type C top-dress medicated feed,'' ''Type C free-choice medicated feed,'' or ''Type C liquid free-choice medicated feed''.

(3) *VFD cautionary statement.* The requirements of paragraph (a)(2) of this section apply.

(4) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(5) ''*Indications for Use*''. The requirements of § 201.407(a)(3) apply. Include only the approved or conditionally approved indications for use for the specific Type C medicated feed to which the representative Type C medicated feed labeling applies.

(6) *Extralabel use statement.* The requirements of paragraph (a)(6) of this section apply.

(7) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the representative Type C medicated feed labeling must include the following information for the specific Type C medicated feed to which the representative Type C medicated feed labeling applies. If the Type C medicated feed contains one active ingredient, this section of the representative Type C medicated feed labeling must be entitled ''Active Ingredient.'' If the Type C medicated feed contains more than one active ingredient, this section of the representative Type C medicated feed labeling must be entitled ''Active Ingredients.''

(i) The established name of each active ingredient; and

(ii) The concentration or range of concentrations of each active ingredient as approved by FDA. If included as a range, the active ingredient concentrations must reference a footnote at the bottom of this page of the representative Type C medicated feed labeling indicating that each final printed Type C medicated feed label must only include a single concentration of each active ingredient.

(8) ''*Guaranteed Analysis*''. The requirements of paragraph (b)(9) of this section apply.

(9) ''*Ingredients*''. This section of the representative Type C medicated feed labeling must include the following:

(i) For Type C medicated feeds that are not Type C free-choice medicated feeds:

(A) A statement that feed ingredients must be listed on each final printed Type C medicated feed label by their common or usual names in descending order of predominance by weight, in accordance with § 501.4(a) of this chapter, including their collective names where permitted, in accordance with § 501.4(b)(13) of this chapter; and

(B) A statement that spices, flavorings, colorings, and chemical preservatives, if used, must be declared on each final printed Type C medicated feed label, in accordance with § 501.22 of this chapter.

(ii) For Type C free-choice medicated feeds, a list of the feed ingredients and their inclusion rates, including the drug concentrations exactly as they appear in the approved non-proprietary formula published for the specific new animal drug in part 558 of this chapter.

(10) ''*Feeding Directions*''. The requirements of paragraph (a)(9)(iii) of this section apply. This section of the representative Type C medicated feed labeling must include the approved feeding directions for the specific Type C medicated feed for which the representative Type C medicated feed labeling applies.

(11) ''*Warnings*''. The requirements of paragraph (a)(10) of this section apply. Include only the warnings for the specific Type C medicated feed to which the representative Type C medicated feed labeling applies.

(12) ''*Additional Recommendations*''. The requirements of § 201.407(a)(8) apply. Include only the precautions for the specific Type C medicated feed to which the representative Type C medicated feed labeling applies.

(13) ''*Other Effects You May Notice*''. The requirements of § 201.407(a)(9) apply. Include only statements of other effects for the specific Type C medicated feed to which the representative Type C medicated feed labeling applies.

(14) *Name and place of business.* This section of the representative Type C medicated feed labeling must provide for the name and place of business of the manufacturer, packer, or distributor of the final Type C medicated feed, in accordance with § 501.5 of this chapter.

(15) ''*Net Weight*''. This section of the representative Type C medicated feed labeling must provide for the statement of net weight on the final printed Type C medicated feed label of the Type C medicated feed in the immediate container.

(16) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(17) ''*Questions/Comments?*''. The following statements must be included in this section of the representative Type C medicated feed labeling: ''Contact [name of business] at [business telephone number] or [business web address]. For additional information about reporting side effects or other problems with medicated feeds, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' The information in the bracketed areas of the first statement are placeholders for the business of the manufacturer, packer, or distributor of the final Type C medicated feed to insert their name and contact information. The information in the bracketed areas of the second statement must be inserted by the sponsor of the new animal drug application.

(18) ''*Lot, Batch, or Control Number*''. This section of the representative Type C medicated feed labeling must provide for an identifying lot, batch, or control number on the final printed Type C medicated feed label.

(19) ''*Expiration Date*''. If an expiration date is required, in accordance with § 514.1(b)(5)(x) of this chapter, then this section of the representative Type C medicated feed labeling must provide for the expiration date to be printed on the final printed Type C medicated feed label. The approved expiration period must also be included in this section of the representative Type C medicated feed labeling.

(20) ''*Revision Date*''. This section of representative Type C medicated feed labeling must include the date of the most recent revision of the representative Type C medicated feed labeling, listing the month followed by the year.

(d) *Proprietary Type B medicated feed label.* The following information, as applicable, must appear in the order listed on the proprietary Type B medicated feed label. Section headings, subsection headings, and other text

presented in quotations in this paragraph must appear verbatim on the proprietary Type B medicated feed label. Sections and subsections are not numbered on the proprietary Type B medicated feed label.

(1) *Proprietary Type B medicated feed identification.* This section of the proprietary Type B medicated feed label must include in order:

(i) Proprietary name of the Type B medicated feed; and

(ii) Established name of the Type B medicated feed. The established name of the Type B medicated feed must include in the following order:

(A) The active moiety or active ingredient of each new animal drug, as determined by FDA; and

(B) One of the following statements, as applicable: ''Type B medicated feed'' or ''Type B liquid medicated feed''.

(2) *VFD cautionary statement.* The requirements of paragraph (a)(2) of this section apply.

(3) *Undiluted statement.* This section of the proprietary Type B medicated feed label must include the statement: ''Do Not Feed Undiluted''.

(4) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(5) ''*Indications for Use*''. The requirements of § 201.407(a)(3) apply.

(6) *Extralabel use statement.* The requirements of paragraph (a)(6) of this section apply.

(7) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the proprietary Type B medicated feed label must include the established name and concentration of each active ingredient in the proprietary Type B medicated feed. If the proprietary Type B medicated feed contains one active ingredient, this section of the proprietary Type B medicated feed label must be entitled ''Active Ingredient.'' If the proprietary Type B medicated feed contains more than one active ingredient, this section of the proprietary Type B medicated feed label must be entitled ''Active Ingredients.''

(8) ''*Guaranteed Analysis*''. This section of the proprietary Type B medicated feed label must provide the nutritional content guarantees of the proprietary Type B medicated feed appropriate for the target animal(s) in addition to any other required specifications.

(9) ''*Ingredients*''. This section of the proprietary Type B medicated feed label must include:

(i) A listing of the feed ingredients in the proprietary Type B medicated feed by their common or usual names in descending order of predominance by weight, in accordance with § 501.4(a) of this chapter, including their collective names where permitted, in accordance with § 501.4(b)(13) of this chapter; and

(ii) A declaration of spices, flavorings, colorings, and chemical preservatives, if used, in accordance with § 501.22 of this chapter.

(10) ''*Mixing Directions*''. This section of the proprietary Type B medicated feed label must provide the approved mixing directions for the manufacture of a Type C medicated feed(s) or another Type B medicated feed(s), as applicable, from the proprietary Type B medicated feed.

(11) ''*Warnings*''. The requirements of paragraph (a)(10) of this section apply.

(12) ''*Additional Recommendations*''. The requirements of § 201.407(a)(8) apply.

(13) ''*Other Effects You May Notice*''. The requirements of § 201.407(a)(9) apply.

(14) ''*Net Weight*''. This section of the proprietary Type B medicated feed label must list the net weight of the Type B medicated feed in the immediate container.

(15) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(16) ''*Questions/Comments?*''. The following statements must be included in this section of the proprietary Type B medicated feed label: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. For additional information about reporting problems with medicated feeds, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Use as the name of the business the manufacturer, packer, or distributor identified in the ''Name and place of business'' section of the proprietary Type B medicated feed label according to paragraph (d)(18) of this section. If more than one business is identified in the ''Name and place of business'' section of the proprietary Type B medicated feed label, select the most appropriate to identify as the ''business'' in the ''Questions/Comments?'' section of the proprietary Type B medicated feed label to provide additional information about the Type B medicated feed and to contact regarding problems with this medicated feed.

(17) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(18) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(19) ''*Lot, Batch, or Control Number*''. This section of the proprietary Type B medicated feed label must include the identifying lot, batch, or control number of the Type B medicated feed. Alternatively, this section must refer to the location on the proprietary Type B medicated feed label or immediate container where the lot, batch, or control number is printed.

(20) ''*Expiration Date*''. If an expiration date is required, in accordance with § 514.1(b)(5)(x) of this chapter, this section must be included on the proprietary Type B medicated feed label and must provide the expiration date of the proprietary Type B medicated feed. Alternatively, this section must refer to the location on the proprietary Type B medicated feed label or immediate container where the expiration date is printed.

(21) ''*Revision Date*''. This section of the proprietary Type B medicated feed label must include the date of the most recent revision of the proprietary Type B medicated feed label, listing the month followed by the year.

(e) *Proprietary Type C medicated feed label.* The following information, as applicable, must appear in the order listed on the proprietary Type C medicated feed label. Section headings, subsection headings, and other text presented in quotations in this paragraph must appear verbatim on the proprietary Type C medicated feed label. Sections and subsections are not numbered on the proprietary Type C medicated feed label.

(1) *Proprietary Type C medicated feed identification.* This section of the proprietary Type C medicated feed label must include in order:

(i) Proprietary name of the Type C medicated feed; and

(ii) Established name of the Type C medicated feed. The established name of the Type C medicated feed must include in the following order:

(A) The active moiety or active ingredient of each new animal drug, as determined by FDA; and

(B) One of the following statements, as applicable: ''Type C medicated feed,'' ''Type C liquid medicated feed,'' ''Type C top-dress medicated feed,'' ''Type C free-choice medicated feed,'' or ''Type C liquid free-choice medicated feed.''

(2) *VFD cautionary statement.* The requirements of paragraph (a)(2) of this section apply.

(3) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(4) ''*Indications for Use*''. The requirements of § 201.407(a)(3) apply.

(5) *Extralabel use statement.* The requirements of paragraph (a)(6) of this section apply.

(6) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the proprietary Type C medicated feed label must include the established name and concentration of each active ingredient in the proprietary Type C medicated feed. If the proprietary Type C medicated feed contains one active ingredient, this section of the proprietary Type C medicated feed label must be entitled ''Active Ingredient.'' If the proprietary Type C medicated feed contains more than one active ingredient, this section of the proprietary Type C medicated feed label must be entitled ''Active Ingredients.''

(7) ''*Guaranteed Analysis*''. The requirements of paragraph (d)(8) of this section apply.

(8) ''*Ingredients*''. The requirements of paragraph (d)(9) of this section apply.

(9) ''*Feeding Directions*''. This section of the proprietary Type C medicated feed label must include the approved feeding directions for the proprietary Type C medicated feed.

(10) ''*Warnings*''. The requirements of paragraph (a)(10) of this section apply.

(11) ''*Additional Recommendations*''. The requirements of § 201.407(a)(8) apply.

(12) ''*Other Effects You May Notice*''. The requirements of § 201.407(a)(9) apply.

(13) ''*Net Weight*''. This section of the proprietary Type C medicated feed label must list the net weight of the Type C medicated feed in the immediate container.

(14) ''*Storage, Handling, and Disposal*''. The requirements of § 201.405(a)(20) apply.

(15) ''*Questions/Comments?*''. The following statements must be included in this section of the proprietary Type C medicated feed label: ''Contact [insert name of business] at [insert business telephone number] or [insert business web address]. For additional information about reporting side effects or other problems with medicated feeds, contact FDA at [insert current FDA telephone number for voluntary reporting of adverse drug experiences] or [insert current FDA web address for voluntary reporting of adverse drug experiences].'' Use as the name of the business the manufacturer, packer, or distributor identified in the ''Name and place of business'' section of the proprietary Type C medicated feed label according to paragraph (e)(17) of this section. If more than one business is identified in the ''Name and place of business'' section of the proprietary Type C medicated feed label, select the most appropriate to identify as the ''business'' in the ''Questions/Comments?'' section of the proprietary Type C medicated feed label to provide additional information about the Type C medicated feed and to contact regarding suspected adverse drug experiences.

(16) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(17) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(18) ''*Lot, Batch, or Control Number*''. This section of the proprietary Type C medicated feed label must include the identifying lot, batch, or control number of the Type C medicated feed. Alternatively, this section must refer to the location on the proprietary Type C medicated feed label or immediate container where the lot, batch, or control number is printed.

(19) ''*Expiration Date*''. If an expiration date is required, in accordance with § 514.1(b)(5)(x) of this chapter, this section must be included on the proprietary Type C medicated feed label and must provide the expiration date of the proprietary Type C medicated feed label. Alternatively, this section must refer to the location on the proprietary Type C medicated feed label or immediate container where the expiration date is printed.

(20) ''*Revision Date*''. This section of the proprietary Type C medicated feed label must include the date of the most recent revision of the proprietary Type C medicated feed label, listing the month followed by the year.

(f) *Other approved labeling for Type A medicated articles.* If other approved labeling associated with approved or conditionally approved Type A medicated articles is provided (other approved labeling for Type A medicated articles), such as shipping labeling, the following information, as applicable, must appear in the order listed on the other approved labeling for Type A medicated articles. Section headings and other text presented in quotations in this paragraph must appear verbatim on the other approved labeling for Type A medicated articles. Sections are not numbered on other approved labeling for Type A medicated articles.

(1) *Type A medicated article identification.* This section of the other approved labeling for Type A medicated articles must include in order:

(i) Proprietary name of the Type A medicated article; and

(ii) Established name of the Type A medicated article.

(2) *VFD cautionary statement.* The requirements of paragraph (a)(2) of this section apply.

(3) ''*Active Ingredient*'' *or* ''*Active Ingredients*''. This section of the other approved labeling for Type A medicated articles must provide the established name and concentration of each active ingredient in the Type A medicated article. If the Type A medicated article contains one active ingredient, this section of the other approved labeling for Type A medicated articles must be entitled ''Active Ingredient.'' If the Type A medicated article contains more than one active ingredient, this section of the other approved labeling for Type A medicated articles must be entitled ''Active Ingredients.''

(4) *Conditional approval statement.* The requirements of § 201.405(a)(3) apply.

(5) ''*Net Contents*''. This section of the other approved labeling for Type A medicated articles must identify the contents of the container to which the other approved labeling for Type A medicated articles applies.

(6) ''*Storage and Handling*''. This section of the other approved labeling for Type A medicated articles must include storage information for the Type A medicated article. If required by FDA to facilitate the drug's safe and effective use, also include handling information.

(7) *NADA/ANADA approval statement.* For approved new animal drugs or approved generic new animal drugs, the requirements of § 201.405(a)(21) apply.

(8) *Name and place of business.* The requirements of § 201.405(a)(22) apply.

(9) ''*Lot Number and Expiration Date*''. This section of the other approved labeling for Type A medicated articles must include the identifying lot or control number(s) and the expiration date(s) of the Type A medicated article within the container.

(10) ''*Revision Date*''. This section of the other approved labeling for Type A medicated articles must include the date of the most recent revision of the other approved labeling for Type A medicated articles, listing the month followed by the year.

§ 201.411 Exemptions from labeling requirements for approved or conditionally approved new animal drugs.

(a) In response to a request from the sponsor that includes the information in paragraph (b) of this section, FDA may exempt, based on the circumstances presented, one or more specific requirements set forth in this subpart. A separate request must be submitted for each approved or conditionally approved new animal drug for which an

exemption is sought. Sponsors must submit such requests to the application or the investigational new animal drug file (INAD) for the new animal drug. Requests will be granted or denied by the Director of FDA's Center for Veterinary Medicine or the Director's designee.

(b) Exemption requests must:

(1) Describe why the particular requirement for which the exemption is requested is not appropriate for the new animal drug;

(2) Describe why granting the exemption would not adversely impact the safety or effectiveness of the use of the new animal drug; and

(3) Include copies of all draft labeling proposed to be used for the new animal drug.

§ 201.413 Labeling requirements for certain approved or conditionally approved new animal drugs.

In addition to labeling requirements elsewhere in this subpart, the labeling requirements in this section apply to the following approved or conditionally approved new animal drugs:

(a) *Approved or conditionally approved corticosteroid-containing new animal drugs for oral, injectable, and/or ophthalmic use.* Approved or conditionally approved corticosteroid-containing new animal drugs for oral, injectable, and/or ophthalmic use are subject to the labeling requirements for Rx new animal drugs in this subpart. In view of adverse reproductive effects associated with use of certain corticosteroid drugs in animals, approved or conditionally approved corticosteroid new animal drugs intended for oral and/or injectable use must also include the following statements in the ''Animal Safety Warnings and Precautions'' subsection of labeling: ''Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids administered during pregnancy can be teratogenic.'' These statements must also be included in the ''Animal Safety Warnings and Precautions'' subsection of labeling for approved or conditionally approved corticosteroid new animal drugs intended for ophthalmic use, if required by FDA to facilitate the drug's safe and effective use.

(b) *Anthelmintic new animal drugs—*(1) *OTC anthelmintic new animal drugs.* To ensure that OTC anthelmintic new animal drugs provide adequate directions for their effective use, all approved or conditionally approved OTC anthelmintic new animal drugs, including OTC anthelmintic new animal drugs for use in animal feeds, must include the following statement in the ''Additional Recommendations'' section of labeling: ''Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.''

(2) *Anthelmintic new animal drugs for use in sheep, goats, cattle, horses, swine, and/or poultry.* All approved or conditionally approved anthelmintic new animal drugs for use in sheep, goats, cattle, horses, swine, and/or poultry must include statements on their labeling providing information to end users to minimize antiparasitic resistance development, including information on appropriate dosing, anthelmintic drug selection, effectiveness monitoring, the integration of anthelmintic drug use with other parasite management practices, and other information as needed. The statements must be included in the ''Other Warnings'' subsection of labeling, and if applicable, additional statements may be required in the ''Dosage and Administration'' section of labeling for Rx anthelmintic new animal drugs, the ''Directions'' section of labeling for OTC anthelmintic new animal drugs, or the ''Feeding Directions'' section or subsection of labeling for anthelmintic new animal drugs for use in animal feeds.

(c) *New animal drugs for use in horses.* All new animal drugs approved or conditionally approved for use in horses must include in the ''Other Warnings'' subsection of labeling a statement advising against the use of the drug in horses intended for human consumption.

PART 500—GENERAL

■ 6. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

§§ 500.25 and 500.55 [Removed]

■ 7. Remove §§ 500.25 and 500.55.

PART 501—ANIMAL FOOD LABELING

■ 8. The authority citation for part 501 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

■ 9. Add § 501.19 to subpart A to read as follows:

§ 501.19 Animal food; labeling of animal food containing new animal drugs.

The requirements for the labeling of animal food containing an approved or conditionally approved new animal drug are found in § 201.409 of this chapter. Requirements of this part apply only as specified in § 201.409.

PART 510—NEW ANIMAL DRUGS

■ 10. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§§ 510.105, 510.106, and 510.410 [Removed]

■ 11. Remove §§ 510.105, 510.106, and 510.410.

PART 514—NEW ANIMAL DRUG APPLICATIONS

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

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

■ 13. In § 514.1, revise paragraph (b)(3) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(3) *Labeling.* Three copies of each piece of all labeling to be used for the article (total of 9).

(i) All labeling should be identified to show its position on, or the manner in which it is to accompany the market package.

(ii) The content and format of all proposed labeling must comply with subpart H of part 201 of this chapter.

(iii) Labeling for nonprescription new animal drugs should include adequate directions for use by the layperson under all conditions of use for which the new animal drug is intended, recommended, or suggested in any of the labeling or advertising sponsored by the applicant.

(iv) Labeling for prescription new animal drugs should bear adequate information for use under which veterinarians can use the new animal drug safely and for the purposes for which it is intended, including those purposes for which it is to be advertised or represented, in accord with § 201.105 of this chapter.

(v) All labeling for prescription or nonprescription new animal drugs must be submitted with any necessary use restrictions prominently and conspicuously displayed.

(vi) Labeling for new animal drugs intended for use in the manufacture of medicated feeds must include:

(A) Specimens of labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested in any of the labeling, including advertising, sponsored by the applicant. Ingredient labeling may utilize collective names as provided in § 501.110 of this chapter.

(B) Representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug.

(vii) Draft labeling may be submitted for preliminary consideration of an application. Final printed labeling will ordinarily be required prior to approval of an application. Proposed advertising for prescription new animal drugs may be submitted for comment or approval.

* * * * *

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 14. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 15. In § 516.155, redesignate paragraph (c) as paragraph (d) and add a new paragraph (c) to read as follows:

§ 516.155 Labeling of indexed drugs.

* * * * *

(c) To ensure that OTC anthelmintic new animal drugs provide adequate directions for their effective use, the labeling of all OTC indexed anthelmintic drugs, including those used in animal feeds, must include the following statement: ''Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.'' The labeling revisions required for compliance with this section may be placed into effect without prior granting of a request for a modification, as provided for in § 516.161(b)(1).

* * * * *

Dated: March 1, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–04840 Filed 3–8–24; 8:45 am]

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