**REGULATORY INFORMATION SERVICE CENTER**

**Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions—Fall 2021**

**AGENCY:** Regulatory Information Service Center.

**ACTION:** Introduction to the Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions.

**SUMMARY:** Publication of the Fall 2021 Unified Agenda of Federal Regulatory and Deregulatory Actions represents a key component of the regulatory planning mechanism prescribed in Executive Order (“E.O.”) 12866, “Regulatory Planning and Review,” (58 FR 51735) and reaffirmed in E.O. 13563, “Improving Regulation and Regulatory Review,” (76 FR 3821). The Regulatory Flexibility Act requires that agencies publish semiannual regulatory agendas in the Federal Register describing regulatory actions they are developing that may have a significant economic impact on a substantial number of small entities (5 U.S.C. 602).

The Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), published in the fall and spring, helps agencies fulfill all of these requirements. All federal regulatory agencies have chosen to publish their regulatory agendas as part of this publication. The complete Unified Agenda and Regulatory Plan can be found online at www.reginfo.gov and a reduced print version can be found in the Federal Register. Information regarding obtaining printed copies can also be found on the Reginfo.gov website (or below, VI. How Can Users Get Copies of the Plan and the Agenda?).

The Fall 2021 Unified Agenda publication appearing in the Federal Register includes the Regulatory Plan and agency regulatory flexibility agendas, in accordance with the publication requirements of the Regulatory Flexibility Act. Agency regulatory flexibility agendas contain only those Agenda entries for rules that are likely to have a significant economic impact on a substantial number of small entities and entries that have been selected for periodic review under section 610 of the Regulatory Flexibility Act.

The complete Fall 2021 Unified Agenda contains the Regulatory Plans of 27 Federal agencies and 67 Federal agency regulatory agendas.

**ADDRESSES:** Regulatory Information Service Center (MR), General Services Administration, 1800 F Street NW, Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:** For further information about specific regulatory actions, please refer to the agency contact listed for each entry. To provide comment on or to obtain further information about this publication, contact: Boris Arratia, Director, Regulatory Information Service Center (MR), General Services Administration, 1800 F Street NW, Washington, DC 20405, 703–795–0816. You may also send comments to us by email at: RISC@gsa.gov.

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Introduction to the Fall 2021 Regulatory Plan

Agency Regulatory Plans

Cabinet Departments

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of the Interior
Department of Labor
Department of Transportation
Department of the Treasury

Other Executive Agencies

Committee for Purchase From People Who Are Blind or Severely Disabled
Environmental Protection Agency
General Services Administration
Office of Management and Budget
Office of Personnel Management
Small Business Administration
Joint Authority
Department of Defense/General Services Administration/National Aeronautics and Space Administration (Federal Acquisition Regulation)

Independent Regulatory Agencies

Consumer Financial Protection Bureau
Consumer Product Safety Commission
Federal Communications Commission
Federal Reserve System
National Labor Relations Board
Nuclear Regulatory Commission
Securities and Exchange Commission
Surface Transportation Board

Introduction to the Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions

I. What are the Regulatory Plan and the Unified Agenda?

The Regulatory Plan serves as a defining statement of the Administration’s regulatory and deregulatory policies and priorities. The Plan is part of the fall edition of the Unified Agenda. Each participating agency’s regulatory plan contains: (1) A narrative statement of the agency’s regulatory and deregulatory priorities, and, for the most part, (2) a description of the most important significant regulatory and deregulatory actions that the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year. This edition includes the regulatory plans of 30 agencies.

The Unified Agenda provides information about regulations that the Government is considering or reviewing. The Unified Agenda has appeared in the Federal Register twice each year since 1983 and has been available online since 1995. The complete Unified Agenda is available to the public at www.reginfo.gov. The online Unified Agenda offers flexible search tools and access to the historic
Unified Agenda database to 1995. The complete online edition of the Unified Agenda includes regulatory agendas from 65 Federal agencies. Agencies of the United States Congress are not included.

The Fall 2021 Unified Agenda publication appearing in the Federal Register consists of The Regulatory Plan and agency regulatory flexibility agendas, in accordance with the publication requirements of the Regulatory Flexibility Act. Agency regulatory flexibility agendas contain only those Agenda entries for rules that are likely to have a significant economic impact on a substantial number of small entities and entries that have been selected for periodic review under section 610 of the Regulatory Flexibility Act. Printed entries display only the fields required by the Regulatory Flexibility Act. Complete agenda information for those entries appears, in a uniform format, in the online Unified Agenda at www.reginfo.gov.

The following agencies have no entries for inclusion in the printed regulatory flexibility agenda. An asterisk (*) indicates agencies that appear in The Regulatory Plan. The regulatory agendas of these agencies are available to the public at www.reginfo.gov.

Cabinet Departments
Department of Justice*
Department of Housing and Urban Development*
Department of State*
Department of Veterans Affairs*
Other Executive Agencies
Agency for International Development
Architectural and Transportation
Barriers Compliance Board
Commission on Civil Rights
Corporation for National and Community Service
Council on Environmental Quality
Court Services and Offender Supervision Agency for the District of Columbia
Federal Mediation Conciliation Service
Institute of Museum and Library Services
Inter-American Foundation
National Aeronautics and Space Administration*
National Archives and Records Administration*
National Endowment for the Arts
National Endowment for the Humanities
National Mediation Board
National Science Foundation
Office of Government Ethics
Office of National Drug Control Policy
Office of Personnel Management*
Peace Corps
Pension Benefit Guaranty Corporation*
Railroad Retirement Board*
Social Security Administration*
Tennessee Valley Authority
U.S. Agency for Global Media

Independent Agencies
Commodity Futures Trading Commission
Council of the Inspectors General on Integrity and Efficiency
Farm Credit Administration
Federal Deposit Insurance Corporation
Federal Energy Regulatory Commission
Federal Housing Finance Agency
Federal Maritime Commission
Federal Mine Safety and Health Review Commission
Federal Permitting Improvement Steering Council
Federal Trade Commission*
National Credit Union Administration
National Indian Gaming Commission*
National Labor Relations Board
National Transportation Safety Board
Postal Regulatory Commission
Council of the Inspectors General on Integrity and Efficiency
Farm Credit Administration
Federal Deposit Insurance Corporation
Federal Energy Regulatory Commission
Federal Housing Finance Agency
Federal Maritime Commission
Federal Mine Safety and Health Review Commission
Federal Trade Commission*
National Credit Union Administration
National Indian Gaming Commission*
National Labor Relations Board
National Transportation Safety Board
Postal Regulatory Commission

The Regulatory Information Service Center compiles the Unified Agenda for the Office of Information and Regulatory Affairs (OIRA), part of the Office of Management and Budget. OIRA is responsible for overseeing the Federal Government’s regulatory, paperwork, and information resource management activities, including implementation of Executive Order 12866 (incorporated in Executive Order 13563). The Center also provides information about Federal regulatory activity to the President and his Executive Office, the Congress, agency officials, and the public.

The activities included in the Agenda are, in general, those that will have a regulatory action within the next 12 months. Agencies may choose to include activities that will have a longer timeframe than 12 months. Agency agendas also show actions or reviews completed or withdrawn since the last Unified Agenda. Executive Order 12866 does not require agencies to include regulations concerning military or foreign affairs functions or regulations related to agency organization, management, or personnel matters.

Agencies prepared entries for this publication to give the public notice of their plans to review, propose, and issue regulations. They have tried to predict their activities over the next 12 months as accurately as possible, but dates and schedules are subject to change.

Agencies may withdraw some of the regulations now under development, and they may issue or propose other regulations not included in their agendas. Agency actions in the rulemaking process may occur before or after the dates they have listed. The Regulatory Plan and Unified Agenda do not create a legal obligation on agencies to adhere to schedules in this publication or to confine their regulatory activities to those regulations that appear within it.

II. Why are the Regulatory Plan and the Unified Agenda published?

The Regulatory Plan and the Unified Agenda helps agencies comply with their obligations under the Regulatory Flexibility Act and various Executive orders and other statutes.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to identify those rules that may have a significant economic impact on a substantial number of small entities (5 U.S.C. 602). Agencies meet that requirement by including the information in their submissions for the Unified Agenda. Agencies may also indicate those regulations that they are reviewing as part of their periodic review of existing rules under the Regulatory Flexibility Act (5 U.S.C. 610). Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” signed August 13, 2002 (67 FR 53461), provides additional guidance on compliance with the Act.

Executive Order 12866

Executive Order 12866, “Regulatory Planning and Review,” September 30, 1993 (58 FR 51735), requires covered agencies to prepare an agenda of all regulations under development or review. The Order also requires that certain agencies prepare annually a regulatory plan of their “most important significant regulatory actions,” which appears as part of the fall Unified Agenda. Executive Order 13497, signed January 30, 2009 (74 FR 6113), revoked the amendments to Executive Order 12866 that were contained in Executive Order 13258 and Executive Order 13422.

Executive Order 13563

Executive Order 13563, “Improving Regulation and Regulatory Review,”
Executive Order 13132

The Executive Order 13132, “Federalism,” August 4, 1999 (64 FR 43255), directs 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” as defined in the Order. Under the Order, an agency that is proposing a regulation with federalism implications, which either preempt State law or impose non-statutory unfunded substantial direct compliance costs on State and local governments, must consult with State and local officials early in the process of developing the regulation. In addition, the agency must provide to the Director of the Office of Management and Budget a federalism summary impact statement for such a regulation, which consists of a description of the extent of the agency’s prior consultation with State and local officials, a summary of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which those concerns have been met. As part of this effort, agencies include in their submissions for the Unified Agenda information on whether their regulatory actions may have an effect on the various levels of government and whether those actions have federalism implications.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–121, title II) established a procedure for congressional review of rules (5 U.S.C. 801 et seq.), which defers, unless exempted, the effective date of a “major” rule for at least 60 days from the publication of the final rule in the Federal Register. The Act specifies that a rule is “major” if it has resulted, or is likely to result, in an annual effect on the economy of $100 million or more or meets other criteria specified in that Act. The Act provides that the Administrator of OIRA will make the final determination as to whether a rule is major.

III. How are the Regulatory Plan and the Unified Agenda organized?

The Regulatory Plan appears in part II in a daily edition of the Federal Register. The Plan is a single document beginning with an introduction, followed by a table of contents, followed by each agency’s section of the Plan. Following the Plan in the Federal Register, as separate parts, are the regulatory flexibility agendas for each agency whose agenda includes entries for rules which are likely to have a significant economic impact on a substantial number of small entities or rules that have been selected for periodic review under section 610 of the Regulatory Flexibility Act. Each printed agenda appears as a separate part. The sections of the Plan end the parts of the Unified Agenda are organized alphabetically in four groups: Cabinet departments; other executive agencies; the Federal Acquisition Regulation, a joint authority (Agenda only); and independent regulatory agencies. Agencies may in turn be divided into subagencies. Each printed agency agenda has a table of contents listing the agency’s printed entries that follow. Each agency’s part of the Agenda contains a preamble providing information specific to that agency. Each printed agency agenda has a table of contents listing the agency’s printed entries that follow.

Each agency’s section of the Plan contains a narrative statement of regulatory priorities and, for most agencies, a description of the agency’s most important significant regulatory and deregulatory actions. Each agency’s part of the Agenda contains a preamble providing information specific to that agency plus descriptions of the agency’s regulatory and deregulatory actions.

The online, complete Unified Agenda contains the preambles of all participating agencies. Unlike the printed edition, the online Agenda has no fixed ordering. In the online Agenda, users can select the particular agencies’ agendas they want to see. Users have broad flexibility to specify the characteristics of the entries of interest to them by choosing the desired responses to individual data fields. To see a listing of all of an agency’s entries, a user can select the agency without specifying any particular characteristics of entries.

Each entry in the Agenda is associated with one or five rulemaking stages. The rulemaking stages are:

1. Prerule Stage—actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations.

2. Proposed Rule Stage—actions for which agencies plan to publish a Notice of Proposed Rulemaking as the next step in their rulemaking process or for which the closing date of the NPRM Comment Period is the next step.

3. Final Rule Stage—actions for which agencies plan to publish a final rule or an interim final rule or to take other final action as the next step.

4. Long-Term Actions—items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda. Some of the entries in this section may contain abbreviated information.
5. Completed Actions—actions or reviews the agency has completed or withdrawn since publishing its last Agenda. This section also includes items the agency began and completed between issues of the Agenda.

6. Long-Term Actions—are rulemakings reported during the publication cycle that are outside of the required 12-month reporting period for which the Agenda was intended. Completed Actions in the publication cycle are rulemakings that are ending their lifecycle either by Withdrawal or completion of the rulemaking process. Therefore, the Long-Term and Completed RINs do not represent the ongoing, forward-looking nature intended for reporting developing rulemakings in the Agenda pursuant to Executive Order 12866, section 4(b) and 4(c). To further differentiate these two stages of rulemaking in the Unified Agenda from active rulemakings, Long-Term and Completed Actions are reported separately from active rulemakings, which can be any of the first three rulemakings listed above. A separate search function is provided on www.reginfo.gov to search for Completed and Long-Term Actions apart from each other and active RINs.

A bullet (•) preceding the title of an entry indicates that the entry is appearing in the Unified Agenda for the first time.

In the printed edition, all entries are numbered sequentially from the beginning to the end of the publication. The sequence number preceding the title of each entry identifies the location of the entry in this edition. The sequence number is used as the reference in the printed table of contents. Sequence numbers are not used in the online Unified Agenda because the unique Regulation Identifier Number (RIN) is able to provide this cross-reference capability.

Editions of the Unified Agenda prior to fall 2007 contained several indexes, which identified entries with various characteristics. These included regulatory actions for which agencies believe that the Regulatory Flexibility Act may require a Regulatory Flexibility Analysis, actions selected for periodic review under section 610(c) of the Regulatory Flexibility Act, and actions that may have federalism implications as defined in Executive Order 13132 or other effects on levels of government. These indexes are no longer compiled, because users of the online Unified Agenda have the flexibility to search for entries with any combination of desired characteristics. The online edition retains the Unified Agenda's subject index based on the Federal Register Thesaurus of Indexing Terms. In addition, online users have the option of searching Agenda text fields for words or phrases.

IV. What information appears for each entry?

All entries in the online Unified Agenda contain uniform data elements including, at a minimum, the following information:

Title of the Regulation—a brief description of the subject of the regulation. In the printed edition, the notation “Section 610 Review” following the title indicates that the agency has selected the rule for its periodic review of existing rules under the Regulatory Flexibility Act (5 U.S.C. 610(c)). Some agencies have indicated completions of section 610 reviews or rulemaking actions resulting from completed section 610 reviews. In the online edition, these notations appear in a separate field.

Priority—an indication of the significance of the regulation. Agencies assign each entry to one of the following five categories of significance.

1. Economically Significant

As defined in Executive Order 12866, a rulemaking action that will have an annual effect on the economy of $100 million or more or will 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, or tribal governments or communities. The definition of an “economically significant” rule is similar but not identical to the definition of a “major” rule under 5 U.S.C. 801 (Pub. L. 104–121). (See below.)

2. Other Significant

A rulemaking that is not Economically Significant but is considered Significant by the agency. This category includes rules that the agency anticipates will be reviewed under Executive Order 12866 or rules that are a priority of the agency head. These rules may or may not be included in the agency’s regulatory plan.

3. Substantive, Nonsignificant

A rulemaking that has substantive impacts, but is neither Significant, nor Routine and Frequent, nor Informational/Administrative/Other.

4. Routine and Frequent

A rulemaking that is a specific case of a multiple recurring application of a regulatory program in the Code of Federal Regulations and that does not alter the body of the regulation.

5. Informational/Administrative/Other

A rulemaking that is primarily informational or pertains to agency matters not central to accomplishing the agency’s regulatory mandate but that the agency places in the Unified Agenda to inform the public of the activity.

Major—whether the rule is “major” under 5 U.S.C. 801 (Pub. L. 104–121) because it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in that Act. The Act provides that the Administrator of the Office of Information and Regulatory Affairs will make the final determination as to whether a rule is major.

Unfunded Mandates—whether the rule is covered by section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). The Act requires that, before issuing an NPRM likely to result in a mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of more than $100 million in 1 year, agencies, other than independent regulatory agencies, shall prepare a written statement containing an assessment of the anticipated costs and benefits of the Federal mandate.

Legal Authority—the section(s) of the United States Code (U.S.C.) or Public Law (Pub. L.) or the Executive order (E.O.) that authorize(s) the regulatory action. Agencies may provide popular name references to laws in addition to these citations.

Citation—the section(s) of the Code of Federal Regulations that will be affected by the action.

Legal Deadline—whether the action is subject to a statutory or judicial deadline, the date of that deadline, and whether the deadline pertains to an NPRM, a Final Action, or some other action.

Abstract—a brief description of the problem the regulation will address; the need for a Federal solution; to the extent available, alternatives that the agency is considering to address the problem; and potential costs and benefits of the action.

Timetable—the dates and citations (if available) for all past steps and a projected date for at least the next step for the regulatory action. A date displayed in the form 12/00/19 means the agency is predicting the month and year the action will take place but not the day it will occur. In some instances, agencies may indicate what the next action will be, but the date of that action is “To Be Determined.” “Next Action Undetermined” indicates the agency does not know what action it will take next.
Regulatory Flexibility Analysis Required—whether an analysis is required by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because the rulemaking action is likely to have a significant economic impact on a substantial number of small entities as defined by the Act.

Small Entities Affected—the types of small entities (businesses, governmental jurisdictions, or organizations) on which the rulemaking action is likely to have an impact as defined by the Regulatory Flexibility Act. Some agencies have chosen to indicate likely effects on small entities even though they believe that a Regulatory Flexibility Analysis will not be required.

Government Levels Affected—whether the action is expected to affect levels of government and, if so, whether the governments are State, local, tribal, or Federal.

International Impacts—whether the regulation is expected to have international trade and investment effects, or otherwise may be of interest to the Nation’s international trading partners.

Federalism—whether the action has “federalism implications” as defined in Executive Order 13132. This term refers to actions “that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

Independent regulatory agencies are not required to supply this information.

Included in the Regulatory Plan—whether the rulemaking was included in the agency’s current regulatory plan published in fall 2021.

Agency Contact—the name and phone number of at least one person in the agency who is knowledgeable about the rulemaking action. The agency may also provide the title, address, fax number, email address, and TDD for each agency contact.

Some agencies have provided the following optional information:

RIN Information URL—the internet address of a site that provides more information about the entry.

Public Comment URL—the internet address of a site that will accept public comments on the entry.

Alternatively, timely public comments may be submitted at the Governmentwide e-rulemaking site, www.regulations.gov.

Additional Information—any information on an agency wishes to include that does not have a specific corresponding data element.

Compliance Cost to the Public—the estimated gross compliance cost of the action.

Affected Sectors—the industrial sectors that the action may most affect, either directly or indirectly. Affected sectors are identified by North American Industry Classification System (NAICS) codes.

Energy Effects—an indication of whether the agency has prepared or plans to prepare a Statement of Energy Effects for the action, as required by Executive Order 13211 “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” signed May 18, 2001 (66 FR 28355).

Related RINs—one or more past or current RIN(s) associated with activity related to this action, such as merged RINs, split RINs, new activity for previously completed RINs, or duplicate RINs.

Statement of Need—a description of the need for the regulatory action.

Summary of the Legal Basis—a description of the legal basis for the action, including whether any aspect of the action is required by statute or court order.

Alternatives—a description of the alternatives the agency has considered or will consider as required by section 4(c)(1)(B) of Executive Order 12866.

Anticipated Costs and Benefits—a description of preliminary estimates of the anticipated costs and benefits of the action.

Risks—a description of the magnitude of the risk the action addresses, the amount by which the agency expects the action to reduce this risk, and the relation of the risk and this risk reduction effort to other risks and risk reduction efforts within the agency’s jurisdiction.

V. Abbreviations

The following abbreviations appear throughout this publication:

ANPRM—An Advance Notice of Proposed Rulemaking is a preliminary notice, published in the Federal Register, announcing that an agency is considering a regulatory action. An agency may issue an ANPRM before it develops a detailed proposed rule. An ANPRM describes the general area that may be subject to regulation and usually asks for public comment on the issues and options being discussed. An ANPRM is issued only when an agency believes it needs to gather more information before proceeding to a notice of proposed rulemaking.

CFR—The Code of Federal Regulations is an annual codification of the general and permanent regulations published in the Federal Register by the agencies of the Federal Government. The Code is divided into 50 titles, each title covering a broad area subject to Federal regulation. The CFR is key to and kept up to date by the daily issues of the Federal Register.

E.O.—An Executive order is a directive from the President to Executive agencies, issued under constitutional or statutory authority. Executive orders are published in the Federal Register and in title 3 of the Code of Federal Regulations.

FR—The Federal Register is a daily Federal Government publication that provides a uniform system for publishing Presidential documents, all proposed and final regulations, notices of meetings, and other official documents issued by Federal agencies.

Public Law—a law is passed by Congress and signed by the President or enacted over his veto. It has general applicability, unlike a private law that applies only to those persons or entities specifically designated. Public laws are numbered in sequence throughout the 2-year life of each Congress; for example, Public Law 112–4 is the fourth public law of the 112th Congress.

Public Comment—A public law is a law passed by Congress and signed by the President or enacted over his veto. It has general applicability, unlike a private law that applies only to those persons or entities specifically designated. Public laws are numbered in sequence throughout the 2-year life of each Congress; for example, Public Law 112–4 is the fourth public law of the 112th Congress.

RFA—A Regulatory Flexibility Analysis is a description and analysis of the impact of a rule on small entities, including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires each agency to prepare an initial RFA for public comment when it is required to publish an NPRM and to make available a final RFA when the final rule is published, unless the agency head certifies that the rule would not have a significant economic impact on a substantial number of small entities.

RIN—The Regulation Identifier Number is assigned by the Regulatory Information Service Center to identify
each regulatory action listed in the Regulatory Plan and the Unified Agenda, as directed by Executive Order 12866 (section 4(b)). Additionally, OMB has asked agencies to include RINs in the headings of their Rule and Proposed Rule documents when publishing them in the Federal Register, to make it easier for the public and agency officials to track the publication history of regulatory actions throughout their development.

Seq. No.—The sequence number identifies the location of an entry in the printed edition of the Regulatory Plan and the Unified Agenda. Note that a specific regulatory action will have the same RIN throughout its development but will generally have different sequence numbers if it appears in different printed editions of the Unified Agenda. Sequence numbers are not used in the online Unified Agenda.

U.S.C.—The United States Code is a consolidation and codification of all general and permanent laws of the United States. The U.S.C. is divided into 50 titles, each title covering a broad area of Federal law.

VI. How can users get copies of the Plan and the Agenda?

Copies of the Federal Register issue containing the printed edition of The Regulatory Plan and the Unified Agenda (agency regulatory flexibility agendas) are available from the Superintendent of Documents, U.S. Government Publishing Office, P.O. Box 371954, Pittsburgh, PA 15250-7954.

Telephone: (202) 512-1800 or 1-866-512-1800 (toll-free).

Copies of individual agency materials may be available directly from the agency or may be found on the agency’s website. Please contact the particular agency for further information.

All editions of The Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions since fall 1995 are available in electronic form at www.reginfo.gov, along with flexible search tools.

The Government Publishing Office’s GPO GovInfo website contains copies of the Agendas and Regulatory Plans that have been printed in the Federal Register. These documents are available at www.govinfo.gov.

Dated: December 7, 2021.

Boris Arratia,
Director.

Introduction to the Fall 2021 Regulatory Plan

Executive Order 12866, issued in 1993, requires the annual production of a Unified Regulatory Agenda and Regulatory Plan. It does so in order to promote transparency—or in the words of the Executive Order itself, “to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President’s priorities and the principles set forth in this Executive order.” The requirements of Executive Order 12866 were reaffirmed in Executive Order 13563, issued in 2011.

We are now providing the first Regulatory Plan of the Biden-Harris Administration for public scrutiny and review. The regulatory plans and agendas submitted by agencies and included here offer blueprints for how the Administration plans to continue delivering on the President’s agenda as we build back better. This agenda is fully consistent with the priorities outlined by the President as reflected in his executive orders and our previous regulatory agenda. We are proud to shine a light on the regulatory agenda as a way to share with the public how the themes of equity, prosperity and public health cut across everything we do to improve the lives of the American people.

These new plans build on significant progress the Administration has already made advancing our priorities and proving that our Government can deliver results—from confronting the pandemic, to creating a stronger and fairer economy, to addressing climate change and advancing equity. For example, since releasing the spring regulatory agenda, we have proposed or finalized regulatory protections to:

• Protect the Public from COVID—The Centers for Disease Control and Prevention (CDC) issued orders requiring all people to wear face masks while on public transportation and in transportation hubs. In addition, CDC issued Global Testing Orders for all international air travelers, strengthening protocols to protect travelers and the health and safety of American communities.

• Combat Housing Discrimination. Following President Biden’s Presidential Memorandum directing his Administration to address racial discrimination in the housing market, the Department of Housing and Urban Development (HUD) published an interim final rule requiring HUD funding recipients to affirmatively further fair housing, including by completing an assessment of fair housing issues, identifying fair housing priorities and goals, and then committing to meaningful actions to meet those goals and remedy identified issues.

• Tackle the Climate Crisis. The Environmental Protection Agency (EPA) took an important step forward to advance President Biden’s commitment to action on climate change and protect people’s health by proposing comprehensive new protections to sharply reduce pollution from the oil and natural gas industry—including, for the first time, reductions from existing sources nationwide. The proposed new Clean Air Act rule would lead to significant, cost-effective reductions in methane emissions and other health-harming air pollutants that endanger nearby communities.

• Improve Pipeline Safety and Environmental Standards. In a major step to enhance and modernize pipeline safety and environmental standards, the Department of Transportation issued a final rule that—for the first time—applies federal pipeline safety regulations to tens of thousands of miles of unregulated gas gathering pipelines. This rule will improve safety, reduce greenhouse gas emissions, and result in more jobs for pipeline workers that are needed to help upgrade the safety and operations of these lines.

In addition to these significant actions, the Administration has also made key progress advancing another core objective: Effectively implementing the American Rescue Plan (ARP). Since the ARP went into effect in March, the Administration has promulgated 17 proposed and 32 final rules to get much needed relief to the communities across the countries efficiently and equitably.

For example:

• The Department of Education established requirements to ensure state and local educational agencies consult members of the public in determining how to use school emergency relief funds, and develop plans for a safe return to in-person instruction.

• The Department of Housing and Urban Development finalized a rule so the agency could require that operators of project-based rental assistance housing (such as Section 8) notify tenants of the availability of emergency rent relief, and give tenants time to secure that relief.

• The Small Business Administration finalized a rule to deliver much needed support to small business by streamlining forgiveness of small loans under the Paycheck Protection Program (a program extended by the ARP Act).

In this agenda, we are adding important new measures under
consideration to advance additional Administration priorities, including:

- **Uncovering Hidden Airline Service Fees.** The Department of Transportation plans to better protect consumers and improve competition by ensuring that consumers have ancillary fee information, including “baggage fees,” “change fees,” and “cancellation fees” at the time of ticket purchase. The Department also plans to examine whether fees for certain ancillary services should be disclosed at the first point in a search process where a fare is listed.

- **Stopping Super-Pollutants.** The EPA is considering restricting—fully, partially, or on a graduated schedule—the use of Hydrofluorocarbons (HFCs) in sectors or subsectors including the refrigeration, air conditioning, aerosol, and foam sectors. HFCs are potent greenhouse gases found in a range of appliances and substances, including refrigerators, air conditioners and foams, and have a profound impact on warming our climate that is hundreds to thousands of times greater than the same amount of carbon dioxide.

- **Transitioning Toward Zero-Emission Technologies.** The EPA plans to strengthen greenhouse gas emission standards for light- and heavy-duty vehicles, with an eye towards encouraging automakers to transition to zero-emission technologies. If implemented, the new standards would save consumers money, cut pollution, boost public health, advance environmental justice, and tackle the climate crisis.

- **Lowering Mental Health and Substance Use Treatment Costs.** The Department of Labor, Department of Health and Human Services, and Department of Treasury are considering changes to clarify health insurance plans' and issuers' obligations to cover mental health and substance use treatment in light of new legislative enactments and experience implementing the MHPAEA law since the last relevant rulemaking in 2014.

- **Increasing Access for People With Disabilities.** As part of the Administration’s commitment to equity, the Department of Justice is exploring a new rule to ensure that individuals with disabilities can use sidewalks and other pedestrian facilities.

Between this regulatory agenda and the next in spring 2022, agencies will also be developing plans for implementing the Infrastructure Investment and Jobs Act (IIJA), historic legislation to rebuild crumbling infrastructure, create good paying jobs, and grow our economy. These plans will provide greater detail on how agencies will administer new IIJA programs in a manner that delivers meaningful results to all Americans, strengthens American manufacturing, and advances climate resilience. These plans will provide an opportunity for the public to be partners in the implementation of the IIJA—and all government programs. Public engagement in IIJA implementation can only make it better and more responsive to what our families and communities most need.

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The U.S. Department of Agriculture’s (USDA) fall 2021 Regulatory Agenda and Plan prioritizes initiatives fostering 21st century innovation, job creation, economic and market opportunity in rural America, particularly among historically underserved people and communities, and a safe end to the pandemic. USDA will continue to leverage existing programs in response to unforeseen events and national emergencies affecting the American farm economy, schools, individual households, and our National Forests. All USDA programs, including the priorities contained in this Regulatory Plan, will be structured to advance the cause of equity by removing barriers and opening new opportunities.

In 2021, the USDA: Agricultural Marketing Service (AMS) implemented a Dairy Donation Program to reimburse dairy organization for donated dairy products to non-profit organizations for distribution to recipient individuals and families. The new program was brought about by the 2020 COVID–19 pandemic which disrupted dairy supply chains and displaced significant volumes of milk normally used in food service channels. This led to milk being dumped or fed to animals across the United States. The new program is intended to encourage the donation of dairy products and to prevent and minimize food waste. Farm Service Agency (FSA) implemented a new Heirs’ Property Relending Program authorized by changes that the Agriculture Improvement Act of 2018 (2018 Farm Bill) made to the Consolidated Farm and Rural Development Act. The relending program provides revolving loan funds to eligible intermediary lenders to resolve ownership and succession on farmland with multiple owners. The lenders give loans to qualified individuals to resolve these ownership issues. The intermediary lenders consolidate and coordinate the ownerships of the land-ownership interests.
Outlined below are some of our most important upcoming regulatory actions. These include efforts to restore and expand economic opportunity amid a safe end to the pandemic; address the climate change emergency; and support agricultural markets that are free, open and promote competition. This Regulatory Plan also reflects USDA’s continued commitments to ensuring a safe and nutritious food supply and animal welfare protections. As always, our Semiannual Regulatory Agenda contains information on a broad-spectrum of USDA’s initiatives and upcoming regulatory actions.

**Restore and Expand Economic Opportunity Amid a Safe End to the Pandemic**

**Pandemic Assistance Programs**

USDA will provide additional direct financial assistance to producers of agricultural commodities who suffered eligible revenue losses in calendar year 2020 during the COVID–19 pandemic; this will expand on the assistance USDA provided last year. Payments will be made using funds under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; Pub. L. 116–136). The rule will also implement the expanded Pandemic Cover Crop Program (PCCP) to help agricultural producers impacted by the effects of the COVID–19 outbreak. Given cover crop cultivation requires sustained, long-term investments to improve soil health and gain other agronomic benefits, the economic challenges due to the pandemic made maintaining cover cropping systems financially challenging for many producers. In addition, the rule will also update the regulations for the Emergency Conservation Program (ECP); the Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP); and the Livestock Forage Disaster Program (LFP); Livestock Indemnity Program (LIP); and payment eligibility provisions. For more information about this rule, see RIN 0503–AA75.

**Address the Climate Change Emergency**

**Special Areas; Roadless Area Conservation; National Forest System Lands in Alaska:** USDA proposes to repeal a final rule promulgated in 2020 that exempted the Tongass National Forest from the 2001 Roadless Area Conservation Rule (2001 Roadless Rule). The 2001 Roadless Rule prohibited timber harvest and road construction or reconstruction within designated Inventoried Roadless Areas, with limited exceptions. This proposal is consistent with President Biden’s Executive Order 13990. **Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,** directing action to address Federal regulations issued during the previous four years that may conflict with protecting the environment and to immediately commence work to confront the climate crisis. For more information about this rule, see RIN 0596–AD51.

**Support Agricultural Markets That Are Free, Open and Promote Competition**

On July 9, 2021, President Biden signed Executive Order 14036 to address the growing concerns over competition and concentration in the U.S. economy, including the agriculture sector. The order includes 72 initiatives by more than a dozen federal agencies including USDA to promptly tackle some of the most pressing competition problems across the economy. Specifically, the White House fact sheet looks to “empower family farmers and increase their incomes by strengthening the Department of Agriculture’s tools to stop the abusive practices of some meat processors.” One of USDA’s initiatives is this area will be to revitalize, through the following rulemakings, the Packers and Stockyards Act to fight unfair practices and rebuild a competitive marketplace:

**Poultry Grower Ranking Systems:** The proposal would address the use of poultry grower ranking systems as a method of payment and settlement grouping for poultry growers under contract in poultry growing arrangements with live poultry dealers. The proposal would establish certain requirements with which a live poultry dealer must comply if a poultry grower ranking system is utilized to determine grower payment. A live poultry dealer’s failure to comply would be deemed an unfair, unjustly discriminatory, and deceptive practice according to factors outlined in the proposed rule. For more information about this rule, see RIN 0581–AE03.

**Clarification of Scope of the Packers and Stockyards Act:** The proposal would revise regulations under the Packers and Stockyards Act (Act), providing clarity regarding conduct that may violate the Act. The proposal would make clear that it is not necessary to demonstrate harm or likely harm to competition to establish a violation of either section 202(a) or (b) of the Act. For more information about this rule, see RIN 0581–AE04.

**Unfair Practices in Violation of the Packers and Stockyards Act:** The proposal supplements recent updates to the regulations issued under the Act that provided criteria for the Secretary to consider when determining whether certain conduct or actions by packers, swine contractors, or live poultry dealers is unduly or unreasonably preferential or advantageous. The proposal clarifies the conduct USDA considers unfair, unjustly discriminatory, or deceptive and a violation of the Act, regardless of whether such action harms or is likely to harm competition. The proposal also clarifies the criteria and types of conduct considered unduly preferential, advantageous, prejudicial, or disadvantageous and violations of the Act. For more information about this rule, see RIN 0581–AE05.

**Ensuring That America’s Food Supply Is Safe and Nutritious**

USDA’s Food Safety and Inspection Service (FSIS) continues to ensure that meat, poultry, and egg products are properly marked, labeled, and packaged, and that the distribution in-commerce of meat, poultry, and egg products that are adulterated or misbranded. Consistent with the President’s priorities of advancing the country’s economic recovery and promoting economic resilience, FSIS is proposing several rules to improve regulatory certainty, which assure consumers that meat, poultry, and egg products are safe and truthfully labeled and fosters fair competition among the regulated industry. In a similar vein, AMS has prepared proposed standards for organic livestock and poultry production.

**Voluntary Labeling of Meat Products With “Product of USA” and Similar Statements:** In accordance with Executive Order 14036, Promoting Competition in the American Economy, FSIS will propose to address concerns that the voluntary “Product of USA” label claim may confuse consumers about the origin of FSIS regulated products. FSIS intends to clarify the voluntary claim so that it is more meaningful to consumers and ensures a fair and competitive marketplace for American farmers and ranchers. For more information about this rule, see RIN 0583–AD87.

**Revision of the Nutrition Facts Panels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed; Prior Label Approval System; Expansion of Generic Label Approval:** FSIS plans to finalize two rules, one to update nutrition labeling for meat and poultry products and another to expand the categories of meat and poultry product labels deemed generically approved that may be used...
in commerce without prior FSIS review and approval. The rule expanding the categories of generically approved labels would reduce labeling costs for meat and poultry establishments, including small and very small establishments. Both rules will provide additional certainty about what is required for meat and poultry labeling while ensuring that consumers have access to the information they need about the food they buy. For more information about these rules, see RINs 0583–AD56 and 0583–AD78.

National Organic Program: Organic Livestock and Poultry Standards: The proposal would establish standards that support additional practice standards for organic livestock and poultry production. This proposed action would add provisions to the USDA organic regulations to address and clarify livestock and poultry living conditions (for example, outdoor access, housing environment and stocking densities), health care practices (for example physical alterations, administering medical treatment, euthanasia), and animal handling and transport to and during slaughter. For more information about this rule, see RIN 0581–AE06.

Animal Welfare Protections

Standards for the Humane Handling, Care, Treatment and Transportation of Birds Not Bred for Use in Research under the Animal Welfare Act: The proposal would establish standards for humane handling, care, treatment, and transportation of birds not bred for use in research when those birds are engaged in any activity covered under the Animal Welfare Act. For more information about this rule, see RIN 0579–AE01.

USDA—AGRICULTURAL MARKETING SERVICE (AMS)

Proposed Rule Stage

1. Poultry Grower Ranking Systems

AMS—FTPP—21–0044

Priority: Other Significant.
Legal Authority: 7 U.S.C. 181 to 229c
CFR Citation: 9 CFR 201.
Legal Deadline: None.
Abstract: The U.S. Department of Agriculture’s Agricultural Marketing Service proposes to amend the regulations issued under the Packers and Stockyards Act (P&S Act) to address the use of poultry grower ranking systems as a method of payment and settlement grouping for poultry growers under contract in poultry growing arrangements with live poultry dealers. The proposed regulation would establish certain requirements with which a live poultry dealer must comply if a poultry grower ranking system is utilized to determine grower payment. A live poultry dealer’s failure to comply would be deemed an unfair, unjustly discriminatory, and deceptive practice.

Statement of Need: Although poultry grower ranking systems may promote healthy competition among growers and the use of improved technologies, differences in size and imbalances of power between parties in contractual poultry growing arrangements can have detrimental effects on one of the contracting parties and may result in marketplace inefficiencies. An often-cited concern is the live poultry dealer’s full control over inputs, e.g., chick, feed, medication, etc., to the poultry growing process. Industry members have asked the Agricultural Marketing Service (AMS) to address such imbalances by specifying the conduct that would be considered violative of the Packers and Stockyards Act (Act).

Summary of Legal Basis: The Agricultural Marketing Service (AMS) is delegated authority by the Secretary of Agriculture to enforce the P&S Act. AMS has received numerous complaints regarding the imbalance of power in poultry growing agreements, wherein one side controls all of the inputs, then arbitrarily ranks grower performance against other growers to determine pay.

Alternatives: AMS considered finalizing a 2016 proposed rule that would have identified criteria for determining whether a live poultry dealer’s use of a grower ranking system for payment purposes might be unlawful under the Packers and Stockyards Act.

Anticipated Cost and Benefits: USDA estimates the first-year costs associated with this proposed rule to be $17.37 million. Subsequent year costs are expected to be significantly less than first-year costs, resulting in a ten-year total cost of $34.64 million. USDA expects the primary benefit of the regulation will be the increased ability to protect poultry growers from unfair practices associated with the use of poultry grower ranking systems. At the same time, the rule is expected to improve efficiencies through the use of new technologies and to reduce market failures among poultry growers.

Risks: Extended litigation over legal challenges from the industry could result in the rule being struck down by the courts, hindering the agency’s ability to enforce the Act for years.

Timetable:

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Regulatory Flexibility Analysis


RIN: 0581–AE03

USDA—AMS

2. Clarification of Scope of the Packers and Stockyards Act (AMS—FTPP—21–0046)

Priority: Other Significant.
Legal Authority: 7 U.S.C. 181 to 229c
CFR Citation: 9 CFR 201.
Legal Deadline: None.
Abstract: USDA proposes to revise the regulations issued under the Packers and Stockyards Act (Act) (7 U.S.C. 181 to 229c) to provide clarity regarding conduct that may violate the Act. This action is intended to support market growth, assure fair trade practices and competition, and protect livestock and poultry growers and producers. The proposed rule addresses long-standing issues related to competitiveness and whether all allegations of violations of the Act must be accompanied by a showing of harm or likely harm to competition.

Statement of Need: Revisions to regulations pertaining to the Packers and Stockyards Act (Act) that would clarify the scope of the Act are needed to establish what conduct or action, depending on their nature and the circumstances, violate the Act without a finding of harm or likely harm to competition. Such revisions reflect the Department of Agriculture’s (USDA) longstanding position in this regard and complement two concurrent rules related to poultry grower ranking systems and conduct that constitutes unfair trade practices under the Act.

Summary of Legal Basis: The Act provides USDA with the authority to assure fair competition and trade practices and to safeguard farmers against receiving less than the true market value of their livestock. Sections 202(c), (d), and (e) of the Act limit the application of those sections to acts or practices that have an adverse effect on competition, such as acts restraining commerce, creating a monopoly, or
producing another type of antitrust injury. However, provisions in sections 202(a) and (b) restrict practices that are deceptive, unfair, unjust, undue, and unreasonable: terms that are understood to encompass more than anticompetitive conduct. USDA’s position is that Congress did not intend application of sections 202(a) and (b) to be limited to instances in which there is harm to competition.

**Alternatives:** USDA considered doing nothing, not challenging standing court decisions. However, courts are not unanimous in their findings. Further, several courts disagree with USDA’s position. Lack of clarity hinders the agency’s ability to consistently administer and enforce the Act.

**Anticipated Cost and Benefits:** USDA estimates annual costs related to this rule of $9 million for the first five years, decreasing in subsequent years, for total ten-year costs of $66 million. We believe the primary benefit of the proposed regulation is the increased ability to protect producers and growers through enforcement of the Act for violations of section 202(a) and/or (b) that do not result in harm, or a likelihood of harm, to competition.

**Risks:** Courts have recognized that the proper analysis of alleged violations of these two sections depends on the facts of each case. However, four courts of appeals have disagreed with USDA’s interpretation of the Act and have concluded that plaintiffs could not prove their claims under those sections without proving harm to competition or likely harm to competition. There is a risk if future legal challenge of USDA interpretation of sections 202(c), (d), and (e) of the Act.

**Summary of Legal Basis:** The Packers and Stockyards Act (Act) authorizes USDA to determine if conduct within the poultry and livestock industries are unfair, unjustly discriminatory, or deceptive and, therefore, a violation of the Act. AMS considers unfair, unjustly discriminatory, or deceptive and a violation of sections 202(a) and (b) to be limited to instances in which there is harm to competition. AMS expects to resolve some of the controversy by being proactive and transparent with the industry to allow for critical discussions and decisions on the rule.

**Regulatory Flexibility Analysis**

**Required:** No.


**USDA—AMS**


Priority: Other Significant.
Abstract: This action would establish additional practice standards for organic livestock and poultry production. This action would add provisions to the USDA organic regulations to address and clarify that livestock and poultry living conditions (for example, outdoor access, housing environment, and stocking densities), health care practices (for example, physical alterations, administering medical treatment, and euthanasia), and animal handling and transport to and during slaughter are part of the organic certification.

Statement of Need: The Organic Livestock and Poultry Standards (OLPS) proposed rule is needed to clarify the USDA organic standards for livestock and poultry living conditions and health practices. The current regulations for livestock production provide general requirements but some of these provisions are ambiguous and have led to inconsistent divergent practices, particularly in the organic poultry sector. This rule responds to nine recommendations from the National Organic Standards Board and findings from a USDA Office of Inspector General (OIG) report. (See USDA, Office of the Inspector General. March 2010. Audit Report 01601–03–Hy, Oversight of the National Organic Program. Available at: http://www.usda.gov/oig/rptsaudit.htm.) This proposed rule includes provisions to support the expression of natural behaviors and the welfare of organic livestock and poultry.

Summary of Legal Basis: OLPS is authorized by the Organic Foods Production Act of 1990 (OPFA), 7 U.S.C. 65016524. OFPA authorizes the USDA to establish national standards governing the marketing of certain agricultural products as organically produced products to assure consumers that organically produced products meet a consistent standard and to facilitate interstate commerce in fresh and processed food that is organically produced.

Alternatives: AMS considered several alternatives and presents these in the proposed rule. AMS presents two compliance date alternatives in the proposed rule that would affect the costs and benefits of the rule. Additionally, AMS discusses alternatives to specific policies included in the proposed rule, including alternative indoor and outdoor space requirements, and non-regulatory alternatives, including consumer education or no rule.

Anticipated Cost and Benefits: AMS estimates an annual cost to broiler producers of approximately $12 million annually and an associated benefit of nearly $100 million annually. The costs of the rule would primarily affect USDA-certified organic operations that produce livestock and poultry. Qualitatively, AMS also anticipates the rule will establish a clear standard protecting the value of the USDA organic seal to consumers, provide a consistent, level playing field for organic livestock producers, and facilitate enforcement of organic livestock and poultry standards.

Risks: A final rule that is very similar to this proposed rule was published on January 19, 2017. That rule was subsequently withdrawn and never became effective. The USDA continues to face two legal challenges related to the withdrawal of the rule. Publishing a new proposed rule will indicate that the USDA is taking steps to advance the regulations. This could be viewed favorably by some, although others would prefer reinstating the January 2017 rule without the associated steps required to finalize a new rule.

The final rule published in January 2017 elicited mixed responses and was opposed by a multitude of producer groups, representing both organic and non-organic producers. Publication of this proposed rule is likely to produce similar responses. Additionally, USDA argued in its withdrawal of the rule that USDA had no authority under the Organic Foods Production Act to promulgate the rule, so there is legal risk in reversing direction and publishing a similar rule.

Finally, AMS plans to seek comment on providing an extended compliance date (15 years) for poultry operations that do not provide birds with access to soil or vegetation in outdoor spaces (i.e., porch systems). AMS’s presentation of this option is likely to invoke strong opinions among some stakeholders.

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Regulatory Flexibility Analysis Required: Undetermined.

Government Levels Affected: Undetermined.


Agency Contact: Lance Bassage, DVM, Director, National Policy Staff, Animal Care, Department of Agriculture, Animal and Plant Health Inspection Service, 4700 River Road, Unit 84, Riverdale, MD 20737, Phone: 518 218–7551, Email: lance.b.bassage@usda.gov.

RIN: 0579–AE61
6. Voluntary Labeling of Meat Products

With “Product of USA” and Similar Statements

Priority: Other Significant.


CFR Citation: 9 CFR 317.8.

Legal Deadline: None.

Abstract: The Food Safety and Inspection Service (FSIS) is proposing to amend its regulations to define the conditions under which the labeling of meat product labels can bear voluntary statements indicating that the product is of United States (U.S.) origin, such as Product of USA, or Made in the USA.

Statement of Need: In 2018 and 2019, FSIS received two petitions requesting that it change its policy regarding the labeling of meat products to indicate U.S. origin. After considering the petitions and the public comments submitted in response to them, FSIS concluded that adherence to the current labeling policy guidance may be causing confusion in the marketplace with respect to certain imported meat and that the current labeling policy may no longer meet consumer expectations of what the Product of USA claim signifies. The Agency wants to ensure that any changes to its current policy are accomplished by an open and transparent process. Therefore, FSIS decided that, instead of changing the Policy Book entry, it would initiate rulemaking to define the conditions under which the labeling of meat products would be permitted to bear voluntary statements indicating that the product is of U.S. origin.


Alternatives: FSIS has considered the current labeling guidance and the alternatives proposed in the two petitions: (1) To amend the FSIS Policy Book to state that meat products may be labeled as Product of USA only if significant ingredients having a bearing on consumer preference such as meat, vegetables, fruits, dairy products, etc., are of domestic origin and; (2) to amend the FSIS Policy Book to provide that any beef product labeled as Made in the USA, Product of the USA, USA Beef or in any other manner that suggests that the origin is the United States, be derived from cattle that have been born, raised, and slaughtered in the United States. FSIS will now be conducting a comprehensive review of origin labeling claims for meat and conducting a consumer perception survey pursuant to developing the proposed regulations.

Anticipated Cost and Benefits: Establishments may incur costs associated with voluntarily changing their labels as a result of any revised Product of USA labeling claim definition. This proposed rule is expected to benefit consumers by providing them more specific information on what Product of USA means for single-ingredient beef and pork products.

Risks: N/A.

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Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: Businesses.

Government Levels Affected: None.

Agency Contact: Matthew Michael, Director, Regulations Development Staff, Department of Agriculture, Food Safety and Inspection Service, Office of Policy and Program Development, 1400 Independence Avenue SW, Washington, DC 20250-3700. Phone: 202 720-0345. Fax: 202 690-0486. Email: matthew.michael@usda.gov.

RIN: 0583-AD87

USDA—FSIS

Final Rule Stage

7. Revision of the Nutrition Facts Panels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed

Priority: Other Significant.


CFR Citation: 9 CFR 317; 9 CFR 381; 9 CFR 413.

Legal Deadline: None.

Abstract: Consistent with the changes that the Food and Drug Administration (FDA) finalized, the Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to update and revise the nutrition labeling requirements for meat and poultry products to reflect recent scientific research and dietary recommendations and to improve the presentation of nutrition information to assist consumers in maintaining healthy dietary practices. The final rule will: (1) Update the list of nutrients that are required or permitted to be declared; (2) provide updated Daily Reference Values (DRV) and Reference Daily Intake (RDI) values that are based on current dietary recommendations from consensus reports; and (3) amend the requirements for foods represented or purported to be specifically for children under the age of four years and pregnant and lactating women and establish nutrient reference values specifically for these population subgroups. FSIS is also revising the format and appearance of the Nutrition Facts Panel; amending the definition of a single-serving container; requiring dual-column labeling for certain containers; and updating and modifying several reference amounts customarily consumed (RACCs or reference amounts). FSIS is also consolidating the nutrition labeling regulations for meat and poultry products into a new Code of Federal Regulations (CFR) part.

Statement of Need: On May 27, 2016, the Food and Drug Administration (FDA) published two final rules: (1) “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (81 FR 33742); and (2) “Food Labeling: Serving Sizes of Foods that Can Reasonably be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (81 FR 34000). FDA finalized these rules to update the Nutrition Facts label to reflect new nutrition and public health research, to reflect recent dietary recommendations from expert groups, and to improve the presentation of nutrition information to help consumers make more informed choices and maintain healthy dietary practices. FSIS has reviewed FDA’s analysis and, to ensure that nutrition information is presented consistently across the food supply, FSIS will propose to amend the nutrition labeling regulations for meat and poultry products to parallel, to the extent possible, FDA’s regulations. This approach will help increase clarity of information to consumers and will improve efficiency in the marketplace.


Alternatives: FSIS is considering different alternatives for the compliance period of the final rule.

Anticipated Cost and Benefits: These proposed regulations are expected to benefit consumers by increasing and improving dietary information available in the market. An estimate of the monetary benefits from these market improvements can be obtained by calculating the medical cost savings generated by linking dietary use to improved consumer diets. In addition, FSIS believes that the public would be
better served by having the regulations governing nutrition labeling consolidated in one part of title 9. Rather than searching through two separate parts of title 9, CFR parts 317 and 381, to find the nutrition labeling regulations, interested parties would only have to survey one, part 413, to be able to apply nutrition panels to their meat and poultry products. Firms would incur a one-time cost for relabeling, recordkeeping costs, and costs associated with voluntary reformulation. Many firms have voluntarily begun using the FDA format, which will reduce costs.

Risks: None.

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Regulatory Flexibility Analysis

Required: No.


Agency Contact: Matthew Michael, Director, Regulations Development Staff, Department of Agriculture, Food Safety and Inspection Service, Office of Policy and Program Development, 1400 Independence Avenue SW, Washington, DC 20250–3700, Phone: 202 720–0345, Fax: 202 690–0486, Email: matthew.michael@usda.gov. RIN: 0583–AD56

USDA—FSIS

8. Prior Label Approval System: Expansion of Generic Label Approval

Priority: Other Significant.


CFR Citation: 9 CFR 412.2 (a) (1); 9 CFR 317.7; 9 CFR 381.128; 9 CFR 412.2 (b).

Legal Deadline: None.

Abstract: The Food Safety and Inspection Service (FSIS) is amending its labeling regulations to expand the categories of meat and poultry product labels that it will deem generically approved and thus not required to be submitted to FSIS. These reforms will reduce the regulatory burden on producers seeking to bring products to market, as well as the Agency costs expended to evaluate the labels.

Statement of Need: This action is needed to reduce the regulatory burden on producers seeking to bring products to market, as well as the Agency costs expended to evaluate the labels. Based on FSIS experience evaluating the labels in question and the ability of inspection personnel to verify labeling in the field, FSIS anticipates this action will have no impact on food safety or the accuracy of meat and poultry product labeling.

Summary of Legal Basis: The Acts direct the Secretary of Agriculture to maintain meat and poultry inspection programs designed to assure consumers that these products are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. Section 7(d) of the Federal Meat Inspection Act (21 U.S.C. 607(d)) states: No article subject to this title shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted. The Poultry Products Inspection Act contains similar language in section 21 U.S.C. 457(c).

Alternatives: FSIS considered three alternatives to the proposed rule: Taking no action, adopting the current proposal except with continued evaluation of labels that would otherwise be generically approved, and allowing all labels to be generically approved.

Anticipated Cost and Benefits: There are no additional costs to industry, or the Agency associated with this rule. FSIS will continue to verify that product labels, including those that are generically approved, are truthful and not misleading and otherwise comply with FSIS’s requirements.

This rule is expected to reduce the number of labels industry is required to submit to FSIS for evaluation by approximately 35 percent. Establishments will realize a cost savings because they will no longer need to incur costs for submitting certain types of labels to FSIS for evaluation (e.g., preparing a printer’s proof). In addition, streamlining the evaluation process for specific types of labels would allow a faster introduction of products into the marketplace by reducing wait times for label approvals.

FSIS will also benefit from a reduction in the number of labels submitted to it for review. FSIS will be able to reallocate staff hours from evaluating labels towards the development of labeling policy.

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Regulatory Flexibility Analysis

Required: No.


Agency Contact: Matthew Michael, Director, Regulations Development Staff, Department of Agriculture, Food Safety and Inspection Service, Office of Policy and Program Development, 1400 Independence Avenue SW, Washington, DC 20250–3700, Phone: 202 720–0345, Fax: 202 690–0486, Email: matthew.michael@usda.gov. RIN: 0583–AD78

BILLING CODE 3101–90–P

DEPARTMENT OF COMMERCE

Statement of Regulatory and Deregulatory Priorities

Established in 1903, the Department of Commerce (Commerce or Department) is one of the oldest Cabinet-level agencies in the Federal Government. Commerce’s mission is to create the conditions for economic growth and opportunity across all American communities by promoting innovation, entrepreneurship, competitiveness, and environmental stewardship. Commerce has 12 operating units, which manage a diverse portfolio of programs and services ranging from trade promotion and economic development assistance to improved broadband access and the National Weather Service, and from standards development and statistical data production, including the decennial census, to patents and fisheries management. Across these varied activities, the Department seeks to provide a foundation for a more equitable, resilient, and globally competitive economy.

To fulfill its mission, Commerce works in partnership with businesses, educational institutions, community organizations, government agencies, and individuals to:

- Innovate by creating new ideas through cutting-edge science and technology, from advances in nanotechnology to ocean exploration to broadband deployment, and by protecting American innovations through the patent and trademark system;
- Support entrepreneurship and commercialization by enabling community development and
strengthening minority businesses and small manufacturers;
• Maintain U.S. economic competitiveness in the global marketplace by promoting exports and foreign direct investment, ensuring a level playing field for U.S. businesses, and ensuring that technology transfer is consistent with our nation’s economic and security interests;
• Provide effective management and stewardship of our nation’s resources and assets to ensure sustainable economic opportunities; and
• Make informed policy decisions and enable better understanding of the economy and our communities by providing timely, accessible, and accurate economic and demographic data.

Responding to the Administration’s Regulatory Philosophy and Principles

Commerce’s Regulatory Plan tracks the most important regulations that the Department anticipates issuing to implement these policy and program priorities and foster sustainable and equitable growth. Of Commerce’s 12 primary operating units, three bureaus—the National Oceanic and Atmospheric Administration (NOAA), the United States Patent and Trademark Office (USPTO), and the Bureau of Industry and Security (BIS)—issue the vast majority of the Department’s regulations, and these three bureaus account for all the planned actions that are considered the Department’s most significant pre-regulatory or regulatory actions for FY 2022.

National Oceanic and Atmospheric Administration

NOAA’s mission is built on three pillars: Science, service, and stewardship—to understand and predict changes in climate, weather, oceans, and coasts; to share that knowledge and information with others; and to conserve and manage coastal and marine ecosystems and resources. At its core, NOAA is a scientific agency. It observes, measures, monitors, and collects data from the depths of the ocean to the surface of the sun, and it does so following principles of scientific integrity. These data are turned into weather and climate models and forecasts that are then used for everything from local weather forecasts to predicting the movement of wildfire smoke to identifying the impacts of climate change on fisheries and living marine resources.

With respect to service, NOAA not only collects data but is mandated to make it operational, and NOAA seeks to be the authoritative provider of climate products and services. By providing Federal, State, and local government partners, the private sector, and the public with actionable environmental information, NOAA can facilitate decisions in the face of climate change. Such decisions can range from businesses planning the location of offices; insurance companies trying to incorporate climate risk into their insurance policies; and municipalities looking to ensure that plans for construction of new housing developments will be resilient to increasing sea level risk, flooding, and heavy precipitation.

The final pillar of NOAA’s mission is stewardship. NOAA seeks to conserve our lands, waters, and natural resources, protecting people and the environment now and for future generations. As part of Commerce, moreover, NOAA recognizes that economic growth must go hand-in-hand with environmental stewardship. For example, with respect to the nation’s fisheries, NOAA looks simultaneously to optimize productivity and ensure sustainability in order to boost long-term economic growth and competitiveness in this vital sector of the U.S. economy. Similarly, national marine sanctuaries both protect important natural resources and also are significant drivers of eco-tourism and local recreation.

Within NOAA, the National Marine Fisheries Services (NMFS) and the National Ocean Service (NOS) are the components that most often exercise regulatory authority. NMFS, the primary operating unit within NOAA’s mission, oversees the management and conservation of the nation’s marine fisheries; protects marine mammals and Endangered Species Act (ESA)-listed marine and anadromous species; and promotes economic development of the U.S. fishing industry. NOS assists the coastal states in their management of land and ocean resources in their coastal zones, including estuarine research reserves; manages national marine sanctuaries; monitors marine pollution; and directs the national program for deep-sea seabed minerals and ocean thermal energy.

Much of NOAA’s rulemaking is conducted pursuant to the following key statutes:

Magnuson-Stevens Fishery Conservation and Management Act

Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) rulemakings concern the conservation and management of fishery resources in the U.S. Exclusive Economic Zone (generally 3–200 nautical miles from shore). As itemized in the Unified Agenda, NOAA plans to take several hundred actions in FY 2022 under Magnuson-Stevens Act authority, of which roughly 20 are expected to be significant rulemakings, as defined in Executive Order 12866. With certain exceptions, rulemakings under Magnuson-Stevens are usually initiated by the actions of eight regional Fishery Management Councils (FMCs or Councils). These Councils are comprised of representatives from the commercial and recreational fishing sectors, environmental groups, academia, and Federal and State government, and they are responsible for preparing fishery management plans (FMPs) and FMP amendments, and for recommending implementing regulations for each managed fishery. FMPs address a variety of issues, including maximizing fishing opportunities on healthy stocks, rebuilding overfished stocks, and addressing gear conflicts. After considering the FMCs’ recommendations in light of the standards and requirements set forth in the Magnuson-Stevens Act and in other applicable laws, NOAA may issue regulations to implement the proposed FMPs and FMP amendments.

Marine Mammal Protection Act

The Marine Mammal Protection Act of 1972 (MMPA) provides the authority for the conservation and management of marine mammals under U.S. jurisdiction. It expressly prohibits, with certain exceptions, the intentional take of marine mammals. The MMPA allows, upon request and subsequent authorization, the incidental take of marine mammals by U.S. citizens who engage in a specified activity (e.g., oil and gas development, pile driving) within a specified geographic region. NMFS authorizes incidental take under the MMPA if it finds that the taking would be of small numbers, have no more than a “negligible impact” on those marine mammal species or stock, and would not have an “unmitigable adverse impact” on the availability of the species or stock for “subsistence” uses. NMFS also initiates rulemakings under the MMPA to establish a management regime to reduce marine mammal mortalities and injuries as a result of interactions with fisheries. In addition, the MMPA allows NMFS to permit the take or import of wild animals for scientific research or public display or to enhance the survival of a species or stock.

Endangered Species Act

The Endangered Species Act of 1973 (ESA) provides for the conservation of
species that are determined to be "endangered" or "threatened," and the conservation of the ecosystems on which these species depend. NMFS and the Department of Interior's Fish and Wildlife Service (FWS) jointly administer the provisions of the ESA: NMFS manages marine and several anadromous species, and FWS manages land and freshwater species. Together, NMFS and FWS work to protect critically imperiled species from extinction. NMFS rulemaking actions under the ESA are focused on determining whether any species under its responsibility is an endangered or threatened species and whether those species must be added to the list of protected species. NMFS is also responsible for designating, reviewing and revising critical habitat for any listed species. In addition, as indicated in the list of highlighted actions below, NMFS and FWS may also issue rules clarifying how particular provisions of the ESA will be implemented.

**The National Marine Sanctuaries Act**

The National Marine Sanctuaries Act (NMSA) authorizes the Secretary of Commerce to designate and protect as national marine sanctuaries areas of the marine environment with special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or aesthetic qualities. The primary objective of the NMSA is to protect marine resources, such as coral reefs, sunken historical vessels, or unique habitats.

NOAA's Office of National Marine Sanctuaries (ONMS), within NOS, has the responsibility for management of national marine sanctuaries. ONMS regulations, issued pursuant to NMSA, prohibit specific kinds of activities, describe and define the boundaries of the designated national marine sanctuaries, and set up a system of permits to allow the conduct of certain types of activities that would otherwise not be allowed.

These regulations can, among other things, regulate and restrict activities that may injure natural resources, including all extractive and destructive activities, consistent with community-specific needs and NMSA's purpose to "facilitate to the extent compatible with the primary objective of resource protection, all public and private uses of the resources of these marine areas." In FY 2022, NOAA is expected to have at least three regulatory actions under NMSA.

**Coastal Zone Management Act**

The Coastal Zone Management Act (CZMA) was passed in 1972 to preserve, protect, and develop and, where possible, to restore and enhance the resources of the nation’s coastal zone. The CZMA creates a voluntary state-federal partnership, where coastal states (States in, or bordering on, the Atlantic, Pacific or Arctic Ocean, the Gulf of Mexico, Long Island Sound, or one or more of the Great Lakes), may elect to develop comprehensive programs that meet federal approval standards. Currently, 34 of the 35 eligible entities are implementing a federally approved coastal management plan approved by the Secretary of Commerce.

**NOAA’s Regulatory Plan Actions**

Of the numerous regulatory actions that NOAA is planning for this year and that are included in the Unified Agenda, there are five, described below, that the Department considers to be of particular importance.

1. **Illegal, Unreported, and Unregulated Fishing: Fisheries Enforcement; High Seas Driftnet Fishing Moratorium Protection Act (0648–BG11):** The United States is a signatory to the Port State Measures Agreement (PSMA). The agreement is aimed at combating illegal, unreported, and unregulated (IUU) fishing activities through increased port inspection of foreign fishing vessels and by preventing the products of illegal fishing from landing and entering into commerce. The High Seas Driftnet Fishing Moratorium Act (Fishing Moratorium Act) implemented provisions of the PSMA, and NOAA issued regulations under the Fishing Moratorium Act in 2011 and 2013. Since then, the provisions of the Fishing Moratorium Act have been amended by the Illegal, Unreported and Unregulated Fishing Enforcement Act of 2015 (Pub. L. 114–81) and the Ensuring Access to Pacific Fisheries Act (Pub. L. 114–327). This proposed rule would implement amendments made by these later two laws. NMFS will also propose changes to the definition of IUU fishing for the purposes of identifying and certifying nations.

2. **Amendments to the North Atlantic Right Whale Vessel Strike Reduction Rule (0648–BB88):** Regulatory modifications are needed to further reduce the likelihood of mortalities and serious injuries to endangered North Atlantic right whales from vessel collisions, which are a primary cause of the species’ decline and greatly contributing to the ongoing Unusual Mortality Event (2017–present). Following two decades of growth, the species has been in decline over the past decade with a population estimate of only 368 individuals as of 2019. Vessel strikes are one of the two primary causes of North Atlantic right whale mortality and serious injury across their range, and human-caused mortality to adult females in particular is limiting recovery of the species. Entanglement in fishing gear is the other primary cause of mortality and serious injury, which is being addressed by separate regulatory actions.

3. **Endangered and Threatened Wildlife and Plants; Revision of the Regulations for Listing Endangered and Threatened Species and Designation of Critical Habitat (0648–BJ44):** This action responds to section 2 of the Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis (E.O. 13990) and the associated Fact Sheet (List of Agency Actions for Review). This is a joint rulemaking by NMFS and the FWS (the Services) to rescind the regulatory definition of the term "habitats." This previously undefined term was defined by regulation for the first time in 2020 for the purpose of designating critical habitat under the ESA. Pursuant to Executive Order 13990, the Services also considered the alternatives of retaining the existing habitat definition or revising the habitat definition and will be considering any alternatives provided during the public comment period on the proposed rule.

4. **Endangered and Threatened Wildlife and Plants; Regulations for Listing Species and Designating Critical Habitat (0648–BK47):** This action responds to section 2 of the Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis (E.O. 13990) and the associated Fact Sheet (List of Agency Actions for Review). This is a joint rulemaking by the Services to revise joint regulations issued in 2019 implementing section 4 of the ESA. Specifically addressed in this action are joint regulations that address the classification of species as threatened or endangered and the criteria and process for designating critical habitat for listed species. Pursuant to Executive Order 13990, the Services reviewed the specific regulatory provisions that had been revised in the 2019 final rule. Following a review of the 2019 rule, the Services are proposing to revise a portion of these regulations but are also soliciting public comments on all aspects of the 2019 rule before issuing a final rule.

5. **Endangered and Threatened Wildlife and Plants; Revision of
Regulations for Interagency Cooperation (0648–BK48): This action responds to section 2 of the Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis (E.O. 13990) and the associated Fact Sheet (List of Agency Actions for Review). This is a joint rulemaking by the Services to revise joint regulations implementing section 7 of the ESA, which requires Federal agencies to consult with the Services whenever any action the agency undertakes, funds, or authorizes may affect endangered or threatened species or their critical habitat, to ensure that the action does not jeopardize listed species or adversely modify critical habitat. In 2019, the Services revised various aspects of the regulations governing the consultation process under ESA Section 7 including, significantly, how the Services define the “effects of the action,” which has importance for determining the scope of consultation. Pursuant to Executive Order 13990, the Services reviewed the specific regulatory provisions that had been revised in the 2019 final rule. Following this review of the 2019 rule, the Services are proposing to revise a portion of these regulations, including “effects of the action,” but are also soliciting public comments on all aspects of the 2019 rule before issuing a final rule. In addition to revising provisions from the 2019 rule, the Services are proposing to clarify the responsibilities of a Federal agency and the Services regarding the requirement to reinstate consultation.

The United States Patent and Trademark Office

The USPTO’s mission is to foster innovation, competitiveness, and economic growth, domestically and abroad, by delivering high quality and timely examination of patent and trademark applications, guiding domestic and international intellectual property policy, and delivering intellectual property information and education worldwide.

Major Programs and Activities

The USPTO is responsible for granting U.S. patents and registering trademarks. This system of secured property rights, which has its foundation in Article I, Section 8, Clause 8, of the Constitution (providing that Congress shall have the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”) has enabled American industry to flourish. New products have been invented, new uses for old ones discovered, and employment opportunities created for millions of Americans. The continued demand for patents and trademarks underscores the importance to the U.S. economy of effective mechanisms to protect new ideas and investments in innovation, as well as the ingenuity of American inventors and entrepreneurs.

In addition to granting patents and trademarks, the USPTO advises the President of the United States, the Secretary of Commerce, and U.S. government agencies on intellectual property (IP) policy, protection, and enforcement; and promotes strong and effective IP protection around the world. The USPTO furthers effective IP protection for U.S. innovators and entrepreneurs worldwide by working with other agencies to secure strong IP provisions in free trade and other international agreements. It also provides training, education, and capacity building programs designed to foster respect for IP and encourage the development of strong IP enforcement regimes by U.S. trading partners.

As part of its work, the USPTO administers regulations located at title 37 of the Code of Federal Regulations concerning its patent and trademark services and the other functions it performs.

The USPTO’s Regulatory Plan Actions

1. Final Rule: Changes to Implement Provisions of the Trademark Modernization Act of 2020 (0651–AD55): The USPTO amends the rules of practice in trademark cases to implement provisions of the Trademark Modernization Act of 2020. This rule establishes ex parte expungement and reexamination proceedings for cancellation of a registration when the required use in commerce of the registered mark has not been made; provides for a new nonuse ground for cancellation before the Trademark Trial and Appeal Board; establishes flexible USPTO action response periods; and amends the existing letter-of-protest rule to indicate that letter-of-protest determinations are final and non-reviewable. The rule also sets fees for petitions requesting institution of ex parte expungement and reexamination proceedings, and for requests to extend USPTO action response deadlines.

The two new ex parte proceedings created by this rulemaking—one for expungement and one for reexamination—are intended to help ensure the accuracy of the trademark register and the availability of new mechanisms for removing a registered mark from the trademark register or cancelling the registration as to certain goods and/or services, when the registrant has not used the mark in commerce. The proposed changes will give U.S. businesses new tools to clear away unused registered trademarks from the federal trademark register and will give the USPTO the ability to move applications through the system more efficiently.

Bureau of Industry and Security

BIS advances U.S. national security, foreign policy, and economic objectives by maintaining and strengthening adaptable, efficient, and effective export control and treaty compliance systems as well as by administering programs to prioritize certain contracts to promote the national defense and to protect and enhance the defense industrial base.

Major Programs and Activities

BIS administers four sets of regulations. The Export Administration Regulations (EAR) regulate exports and reexports to protect national security, foreign policy, and short supply interests. The EAR includes the Commerce Control List (CCL), which describes commodities, software, and technology that are subject to licensing requirements for specific reasons for control. The EAR also regulates U.S. persons’ participation in certain boycotts administered by foreign governments. The National Security Industrial Base Regulations provide for prioritization of certain contracts and allocations of resources to promote the national defense, require reporting of foreign government-imposed offsets in defense sales, provide for surveys to assess the capabilities of the industrial base to support the national defense, and address the effect of imports on the defense industrial base. The Chemical Weapons Convention Regulations implement declaration, reporting, and on-site inspection requirements in the private sector necessary to meet United States treaty obligations under the Chemical Weapons Convention treaty. The Additional Protocol Regulations implement similar requirements for certain civil nuclear and nuclear-related items with respect to an agreement between the United States and the International Atomic Energy Agency.

BIS also has an enforcement component with nine offices covering the United States, as well as BIS export control officers stationed at several U.S. embassies and consulates abroad. BIS works with other U.S. Government agencies to promote coordinated U.S. Government efforts in export controls and other programs. BIS participates in U.S. Government efforts to strengthen...
multilateral export control regimes and promote effective export controls through cooperation with other governments.

In FY 2022, BIS plans to publish a number of proposed and final rules amending the EAR. These rules will cover a range of issues, including emerging and foundational technology, country-specific policies, CCL revisions based on decisions by the four multilateral export control regimes (Australia Group, Missile Technology Control Regime, Nuclear Suppliers Group, and Wassenaar Arrangement), and implementation of any interagency agreed transfers from the United States Munitions List to the CCL.

BIS’s Regulatory Plan Actions

1. Authorization of Certain “Items” to Entities on the Entity List in the Context of Specific Standards Activities (0694–AI06): BIS is amending the EAR to clarify its applicability to releases of technology for standards setting or development to support U.S. participation in standards efforts.

2. Commerce Control List: Implementation of Controls on “Software” Designed for Certain Automated Nucleic Acid Assemblers and Synthesizers (0694–AI08): BIS is publishing this final rule to amend the CCL by adding a new Export Control Classification Number (ECCN) 2D352 to control software that is designed for automated nucleic acid assemblers and synthesizers controlled under ECCN 2B352; and capable of designing and building functional genetic elements from digital sequence data. These amendments to the CCL are based upon a finding, consistent with the emerging and foundational technologies interagency process set forth in section 1758 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4817), that such software is capable of being utilized in the production of pathogens and toxins and, consequently, the absence of export controls on such software could be exploited for biological weapons purposes.

3. Information Security Controls: Cybersecurity Items (0694–AH56): In 2013, the Wassenaar Arrangement (WA), a multilateral export control regime in which the United States participates, added cybersecurity items to the WA List, including a definition for “intrusion software.” In 2015, public comments on a BIS proposed implementation rule revealed serious issues concerning scope and implementation regarding these controls. Based on these comments, as well as substantial commentary from Congress, the private sector, academia, civil society, and others on the potential unintended consequences of the 2013 controls, the U.S. government returned to the WA to renegotiate the controls. This interim final rule outlines the progress the United States has made in this area, revises implementation, and requests from the public information about the impact of these revised controls on U.S. industry and the cybersecurity community. These items warrant controls because these tools could be used for surveillance, espionage, or other actions that disrupt, deny or degrade the network or devices on it.

4. Imposition of Export Controls on Certain Brain-Computer Interface (BCI) Emerging Technology (0694–AF41): Section 1758 of ECRA, as codified under 50 U.S.C. 4817, authorizes BIS to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies. Pursuant to ECRA, BIS has identified Brain Computer Interface technology as part of a representative list of technology categories for which BIS will seek public comment to determine whether this is an emerging technology that is important to the United States national security and for which effective controls can be implemented. In this Advance Notice of Proposed Rulemaking, BIS is seeking comments specifically concerning whether this technology could provide the United States, or any of its adversaries, with a qualitative military or intelligence advantage. In addition, BIS is seeking public comments on how to ensure that the scope of any controls that may be imposed on this technology in the future would be effective and appropriate with respect to their potential impact on legitimate commercial or scientific applications.

5. Foundational Technologies: Proposed Controls (0694–AH80): BIS is considering expanding controls on certain foundational technologies. Foundational Technologies may be items that are currently subject to control for military end use or military end user reasons. Additionally, foundational Technologies may be additional items, for which an export license is generally not required (except for certain countries), that also warrant review to determine if they are foundational technologies essential to the national security. For example, such controls may be reviewed if the items are being utilized or are required for innovation in developing conventional weapons or enabling foreign intelligence collection activities or weapons of mass destruction applications. In an effort to address this concern, this proposed rule would amend the CCL by adding controls on certain aircraft reciprocating or rotary engines and powdered metals and alloys. This rule requests public comments to ensure that the scope of these proposed controls will be effective and appropriate, including with respect to their potential impact on legitimate commercial or scientific applications.

6. Removal of Certain General Approved Exclusions (GAEs) Under the Section 232 Steel and Aluminum Tariff Exclusions Process (0694–AH53): On December 14, 2020, BIS published an interim final rule (the December 14 rule) that revised aspects of the process for requesting exclusions from the duties and quantitative limitations on imports of aluminum and steel discussed in three previous Commerce interim final rules implementing the exclusion process authorized by the President under section 232 of the Trade Expansion Act of 1962, as amended (232), as well as a May 26, 2020, notice of inquiry. The December 14 rule added 123 General Approved Exclusions (GAEs) to the regulations. The addition of GAEs was an important step in improving the efficiency and effectiveness of the 232 exclusions process for certain Harmonized Tariff Schedule of the United States (HTSUS) codes for steel and aluminum that had not received objections. Commerce determined it could authorize imports under GAEs for these specified HTSUS codes for all importers instead of requiring each importer to submit an exclusion request. Subsequently, based on Commerce’s review of the public comments received in response to the December 14 rule and additional analysis conducted by Commerce of 232 exclusion request submissions, Commerce determined that a subset of the GAEs added in the December 14 rule did not meet the criteria for inclusion as a GAE and should therefore be removed. Commerce is removing these GAEs in this interim final rule to ensure that only those GAEs that meet the stated criteria from the December 14 rule will continue to be included as eligible GAEs. Lastly, this interim final rule makes two conforming changes to the GAE list for a recent change to one HTSUS classification and adds a footnote to both GAE supplements to address future changes to the HTSUS.
9. Request for Comments Concerning the Imposition of Export Controls on Certain Brain–Computer Interface (BCI) Emerging Technology

Prerule Stage

Priority: Other Significant
Legal Authority: 50 U.S.C. 4817(a)(2)(C)
CFR Citation: None
Legal Deadline: None

Abstract: Section 1758 of the Export Control Reform Act of 2018 (ECRA), as codified under 50 U.S.C. 4817, authorizes BIS to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies. Pursuant to ECRA, BIS has identified Brain Computer Interface (BCI) technology as part of a representative list of technology categories concerning which BIS, through an interagency process, seeks public comment to determine whether this technology represents an emerging technology that is important to U.S. national security and for which effective controls can be implemented. Specifically, BIS is seeking comments concerning whether this technology could provide the United States, or any of its adversaries, with a qualitative military or intelligence advantage. In addition, BIS is seeking public comments on how to ensure that the scope of any controls that may be imposed on this technology in the future would be effective and appropriate (with respect to their potential impact on legitimate commercial or scientific applications).

Statement of Need: The Bureau of Industry and Security (BIS) is publishing this ANPRM to obtain public comments on the potential uses of Brain-Computer Interface (BCI) technology, which includes, inter alia, neural-controlled interfaces, mind-machine interfaces, direct neural interfaces, and brain-machine interfaces. On November 19, 2018, BIS published an ANPRM (83 FR 58201) that identified BCI technology as part of a representative list of technology categories concerning which BIS, through an interagency process, sought public comments to determine whether there are specific emerging technologies that are essential to U.S. national security and for which effective controls can be implemented.

Additional input from the public is needed to assist in the interagency process of evaluating BCI technology as a potential emerging technology and to determine if there are specific BCI technologies for which export controls would be appropriate. The public’s responses to the questions posed in this ANPRM will be considered during the aforementioned interagency process to evaluate BCI technology as a potential emerging technology and to ensure that the scope of any controls that may be imposed on this technology would be effective (in terms of protecting U.S. national security interests) and appropriate (with respect to minimizing their potential impact on legitimate commercial or scientific applications).

Summary of Legal Basis: Section 1758(a) of the Export Control Reform Act (ECRA) of 2018 (50 U.S.C. 4817(a)) outlines an interagency process for identifying emerging and foundational technologies. BCI technology has been identified as a technology for evaluation as a potential emerging technology, consistent with the interagency process described in section 1758 of ECRA. Consequently, BIS is publishing this ANPRM to obtain feedback from the public and U.S. industry concerning whether such technology could provide the United States, or any of its adversaries, with a qualitative military or intelligence advantage.

Alternatives: The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the section 1758 process. In so doing, the Secretary must consider the potential end-uses and end-users of emerging and foundational technologies, and the countries to which exports from the United States are restricted (e.g., embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum a license must be required for the export of such technologies to countries subject to a U.S. embargo, including those countries subject to an arms embargo.

If the interagency process results in a determination that certain BCI technology constitutes an emerging technology, for purposes of section 1758 of ECRA, then BIS is required, pursuant to ECRA to institute export controls on such technology. However, BIS does have some flexibility to ensure that the scope of any controls that may be imposed on this technology would be effective (in terms of protecting U.S. national security interests) and appropriate (with respect to minimizing their potential impact on legitimate commercial or scientific applications).

Timeframe:

Action Date FR Cite
ANPRM ............... 10/26/21 86 FR 59070
ANPRM Comment Period End. 12/10/21
NPRM ............... 03/00/22

Regulatory Flexibility Analysis
Required: No.
Government Levels Affected: None.
Agency Contact: Willard Fisher, Export Administration Specialist, Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230, Phone: 202 482–2440, Fax: 202 482–3355, Email: willard.fisher@bis.doc.gov
RIN: 0694–A141

DOC—BIS

Proposed Rule Stage

10. Foundational Technologies: Proposed Controls; Request for Comments

Priority: Other Significant
Legal Authority: 50 U.S.C. 4801 to 4852
CFR Citation: 15 CFR 742; 15 CFR 774.
Legal Deadline: None.
Abstract: The Bureau of Industry and Security (BIS), the Department of Commerce, maintains controls on the export, reexport, and transfer (in-country) of dual-use and less sensitive military items through the Export Administration Regulations (EAR), including the Commerce Control List (CCL). Foundational technologies may be items that are currently subject to control for military end use or military
end user reasons. Additionally, foundational technologies may be additional items, for which an export license is not required (except for certain countries) that also warrant review to determine if they are foundational technologies essential to the national security. For example, such controls may be reviewed if the items are being utilized or required for innovation in developing conventional weapons or enabling foreign intelligence collection activities or weapons of mass destruction applications. In an effort to address this concern, this rule proposes to amend the CCL with identified foundational technologies. This rule requests public comments to ensure that the scope of these proposed controls will be effective and appropriate, including with respect to their potential impact on legitimate commercial or scientific applications.

**Statement of Need:** As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2019 (Pub. L. 115–232), Congress enacted the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4817). Section 1758 of ECRA authorizes the Bureau of Industry and Security (BIS) to establish appropriate controls on the export, reexport, or transfer (in-country) of emerging and foundational technologies. With this proposed rule, BIS continues to identify technologies that may warrant more restrictive controls than those at present and establishes a control framework applicable to certain unilaterally-controlled emerging and foundational technologies.

**Summary of Legal Basis:** There are a variety of legal authorities under which BIS operates. However, ECRA (50 U.S.C. 4817) provides the most substantive legal basis for BIS’s actions under this proposed rule.

**Alternatives:** There are not alternatives to this rule. This rule serves as the first tranche of controls specifically outlining foundational technologies.

**Anticipated Cost and Benefits:** The anticipated costs and benefits of this proposed rule are not applicable.

**Risks:** There are no applicable risks to this proposed rule.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No.

**Government Levels Affected:** None.

**International Impacts:** This regulatory action will likely have international trade and investment effects, or otherwise be of international interest.

**Agency Contact:** Logan D. Norton, Department of Commerce, Bureau of Industry and Security, 1401 Constitution Avenue, Washington, DC 20230, Phone: 202 812–1762, Email: logan.norton@bis.doc.gov. RIN: 0694–AH80

**DOC—BIS**

**Final Rule Stage**

11. Removal of Certain General Approved Exclusions (GAEs) Under the Section 232 Steel and Aluminum Tariff Exclusions Process

**Priority:** Other Significant.

**Legal Authority:** 19 U.S.C. 1862

**CFR Citation:** 15 CFR 705.

**Legal Deadline:** None.

**Abstract:** On December 14, 2020, the Department of Commerce published an interim final rule (December 14 rule) that revised aspects of the process for requesting exclusions from the duties and quantitative limitations on imports of aluminum and steel. The December 14 rule added 123 General Approved Exclusions (GAEs) to the regulations. The addition of GAEs was an important step in improving the efficiency and effectiveness of the 232 exclusions process. Commerce identified the need for these GAEs to improve the transparency and effectiveness of the 232 exclusions process for certain Harmonized Tariff Schedule of the United States (HTSUS) codes for steel and aluminum that had not received objections. Subsequently, based on Commerce’s review of the public comments received in response to the December 14 rule and additional analysis conducted by Commerce of 232 submissions, Commerce determined that a subset of the GAEs added in the December 14 rule did not meet the criteria for inclusion as a GAE and should therefore be removed. Commerce is removing these GAEs in today’s interim final rule to ensure that only those GAEs that meet the stated criteria from the December 14 rule will continue to be included as eligible GAEs.

**Statement of Need:** On December 14, 2020, the Department of Commerce published an interim final rule (the December 14 rule) that revised aspects of the process for requesting exclusions from the duties and quantitative limitations on imports of aluminum and steel discussed in three previous Department of Commerce (Commerce) interim final rules implementing the exclusion process authorized by the President under section 232 of the Trade Expansion Act of 1962, as amended (232), as well as a May 26, 2020 notice of inquiry. The December 14 rule included adding 123 General Approved Exclusions (GAEs) to the regulations. The addition of GAEs was an important step in improving the efficiency and effectiveness of the 232 exclusions process. Commerce selected certain steel and aluminum articles under select Harmonized Tariff Schedule of the United States (HTSUS) codes as GAEs on the basis that exclusion requests submitted for the specified HTSUS codes had not received objections from domestic industry in the 232 exclusions process.

Commerce is publishing this interim final rule to remove a subset of General Approved Exclusions (GAEs) added in the December 14 rule after public comments on the December 14 rule and subsequent Commerce analysis of data in the 232 Exclusions Portal identified these HTSUS codes as not meeting the criteria for inclusion as a GAE. These cases include HTSUS codes with exclusion requests that recently received objections and/or denials in the 232 Exclusions Portal. Commerce is removing these GAEs in this interim final rule to ensure that only those GAEs that met the stated criteria from the December 14 rule will continue to be included as eligible GAEs.

**Summary of Legal Basis:** The legal basis of this rule is section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979). This rule is also implementing the directive included in Proclamations 9704 and 9705 of March 8, 2018. As explained in the report submitted by the Secretary to the President, steel and aluminum are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States, and therefore the President is implementing these remedial actions (as described in Proclamations 9704 and 9705 of March 8, 2018) to protect U.S. national security interests. That implementation includes the creation of an effective process by which affected domestic parties can obtain exclusion requests based upon specific national security criteria.
considerations. Commerce started this process with the publication of the March 19 rule and refined the process with the publication of the September 11, June 10, and December 14 rules and is continuing the process with the publication of today’s interim final rule. The revisions to the exclusion request process are informed by the comments received in response to the December 14 rule and Commerce’s experience with managing the 232 exclusions process.

Alternatives: Alternatives to doing this rule would include not publishing the rule. The public has the ability to apply for exclusion requests, so instead of creating GAEs, the public could be told to rely on the existing exclusions process. However, numerous commenters on the 232 interim final rules that have been published have emphasized the need for making improvements in the efficiency, transparency, and fairness of the 232 exclusion process and had suggested the creation of a GAE type of approval as part of the 232 exclusions process.

Commenters on the December 14 rule identified certain GAE eligible items that they believed did not meet the stated criteria for what should be eligible for be authorized under a GAE. Commerce after reviewing those comments and conducting its own additional analysis agrees that certain items identified under the current GAEs no longer reflect the GAE criteria and therefore should be removed, so the alternative of not doing a rule or the option of removing the GAEs completely are not viable options for achieving the intended policy objectives that Commerce is trying to fulfill with having a more effective exclusion process.

Anticipated Cost and Benefits: For the anticipated costs, this rule is expected to increase the burden hours for one of the collections associated with this rule. The increase is expected because of the removal of certain GAEs for steel and aluminum which is expected to result in an increase of 1,100 exclusion request submissions per year.

For the anticipated benefits, these changes will ensure the effectiveness of the GAEs under the 232 exclusion process. By ensuring that only those GAEs that meet the stated criteria for what should be considered a GAE, will help improve the effectiveness, fairness and transparency of the 232 exclusion process. Importers and other users of steel and aluminum have comments in response to the various section 232 interim final rules published that creating an effective 232 exclusion process is key to reduce burdens on the public. The adoption of the GAEs was an important step in improving efficiency, but in order ensure U.S. national security interests are protected, only items that meet the GAE criteria should be eligible and any other item should be required to be included in the normal 232 exclusion process.

Risks: If this interim final rule were to be delayed, companies in the United States would be unable to immediately benefit from the improvements made to the GAE process and could face significant economic hardship, which could potentially create a detrimental effect on the general U.S. economy and national security. Comments received on the December 14 rule that were critical of the GAEs were clear that the removal of certain GAEs that consisted of HTSUS codes that received objections and/or denials under the 232 process was needed. Commenters noted that failure to provide this additional improvement could allow the floodgates to open for imports of those articles, and that the influx of such articles could undermine the efficiency of the 232 process. Commenters also noted that if this specific improvement is not made, significant economic consequences could occur. Given the imports of these articles have already been objected to and/or denied in exclusion requests under the 232 process for national security reasons, allowing these specific GAEs to exist could undermine other critical U.S. national security interests.

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**Regulatory Flexibility Analysis**

Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Agency Contact: Timothy Mooney, Export Policy Analyst, Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230, Phone: 202 482-3371, Fax: 202 482-3355, Email: timothy.mooney@bis.doc.gov.

RIN: 0694–AH55

**DOC—BIS**

12. Information Security Controls:

Cybersecurity Items

**Priority:** Other Significant.


**CFR Citation:** 15 CFR 740; 15 CFR 742; 15 CFR 772; 15 CFR 774.

**Legal Deadline:** None.

**Abstract:** In 2013, the Wassenaar Arrangement (WA) added cybersecurity items to the WA List, including a definition for “intrusion software.” On May 20, 2015, the Bureau of Industry and Security (BIS) published a proposed
rule describing how these new controls would fit into the Export Administration Regulations (EAR) and requested information from the public about the impact on U.S. industry. The public comments on the proposed rule revealed serious issues concerning scope and implementation regarding these controls. Based on these comments, as well as substantial commentary from Congress, the private sector, academia, civil society, and others on the potential unintended consequences of the 2013 controls, the U.S. government returned to the WA to renegotiate the controls. This interim final rule outlines the progress the United States has made in this area, revised Commerce Control List (CCL) implementation, and requests from the public information about the impact of these revised controls on U.S. industry and the cybersecurity community.

**Statement of Need:** In 2013, the Wassenaar Arrangement (WA) added cybersecurity items to the WA List, including a definition for intrusion software. On May 20, 2015, the Bureau of Industry and Security (BIS) published a proposed rule describing how these new controls would fit into the Export Administration Regulations (EAR) and requested information from the public about the impact on U.S. industry. The public comments on the proposed rule revealed serious issues concerning scope and implementation regarding these controls. Based on these comments, as well as substantial commentary from Congress, the private sector, academia, civil society, and others on the potential unintended consequences of the 2013 controls, the U.S. government returned to the WA to renegotiate the controls. This interim final rule outlines the progress the United States has made in this area, implements revised Commerce Control List (CCL) text, establishes a new License Exception Authorized Cybersecurity Exports (ACE) and requests from the public information about the impact of these revised controls on U.S. industry and the cybersecurity community.

**Summary of Legal Basis:** On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801–4852. ECRA provides the legal basis for BIS’s principal authorities and serves as the authority under which BIS issues this rule.

**Alternatives:** As noted above, BIS does not believe that the amendments in this rule, will have a significant economic impact on a substantial number of small entities. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these amendments to assess whether the alternatives would: (1) Accomplish the stated objectives of this rule (consistent with the requirements in ECRA); and (2) minimize any significant economic impact of this rule on small entities. BIS could have implemented a much broader control on software capable of cybersecurity controlled under ECCNs 4A005, 4D004, 4E001, 4E001, and 5A001 that would have captured a greater amount of such software and related technology. That in turn would have had a greater impact not only on small businesses, but also on research and development laboratories (both academic and corporate), which are involved in network security. BIS has determined that implementing focused controls on specific software and related technology (i.e., the software controlled under new ECCN 4A005, 4D004, 4E001.a, 4E001.c, and 5A001.j and corresponding development technology in ECCN 5E001) is the least disruptive alternative for implementing export controls in a manner consistent with controlling technology that has been determined, through the interagency process authorized under ECRA, to be essential to U.S. national security. BIS is not implementing different compliance or reporting requirements for small entities. If a small business is subject to a compliance requirement for the export, reexport or transfer (in-country) of this software and related technology, then it would submit a license application via SNAPR. The license application process is free of charge to all entities, including small businesses. In addition, as noted above, the resources and other compliance tools made available by BIS typically serve to lessen the impact of any EAR license requirements on small businesses.

**Anticipated Cost and Benefits:** For the existing ECCNs included in this rule (4D001, 4E001, 5A001, 5A004, 5D001, 5E001), the U.S. Customs and Border Protection’s Automated Export System (AES) shows 980 shipments valued at $39,146,164. Of those shipments, 120 shipments valued at $1,864,699 went to Country Group D:1 or D:5 countries, which would make them ineligible for License Exception ACE. There were no shipments to Country Group E:1 or E:2. Under the provisions of this rule, the 120 shipments require a license application submission to BIS. As there is no specific ECCN data in AES for the new export controls in new ECCNs 4A005 and 4D004 or new paragraph 4E001.c, BIS uses other data to estimate the number of shipments of these new ECCNs that will require a license. Bureau of Economic Analysis (BEA) data from 2019 show a total dollar value of $55,657 million for Telecom, Computer, and Information Technology Services exports. Multiplying this value by 12.1% (the percentage of all exports that are subject to an EAR license requirement as determined by using AES data) suggests that $6,734,497,000 of Telecom/Computer/IT exports are now subject to EAR license requirements. Based on AES data on the existing ECCNs affected by this rule, BIS estimates the average value of each shipment for the new ECCNs at about $40,000, and further estimates that 0.6% of all new ECCN shipments (1,010 shipments) are now eligible for License Exception ACE and 0.03% of all new ECCN shipments (50 shipments) require a license application submission. Therefore, the annual total estimated cost associated with the paperwork burden imposed by this rule (that is, the projected increase of license application submissions based on the additional shipments requiring a license) is estimated to be 170 new applications × 29.6 minutes = 5,032/60 min = 84 hours × $30 = $2,520. There is no paperwork submission to BIS associated with using License Exception ACE, and therefore there is no increase to any paperwork burden or information collection cost associated with License Exception ACE requirements in this rule.

**Benefit:** Cybersecurity items in the wrong hands raise both national security and foreign policy concerns. The benefit of publishing these revisions and controlling cybersecurity items in the way contemplated by this rule is that national security and foreign policy concerns are addressed, in that these regulations assist in keeping such items out of the hands of those that would use them for nefarious end uses, while at the same time not disrupt legitimate cybersecurity exports.

**Risks:** The risks of publishing this rule is that it has unexpected consequences, which is why there is a 90 day delayed effective date and 45 day comment period that will allow the public to comment on the rule.

**Timetable:**

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Regulatory Flexibility Analysis

**Required:** No.

**Small Entities Affected:** No.

**Government Levels Affected:** None.

**Agency Contact:** Sharron Cook, Policy Analyst, Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230. Phone: 202 482–2440. Fax: 202 482–3355. Email: sharron.cook@bis.doc.gov.

**Related RIN:** Related to 0694–AG49.

**RIN:** 0694–AH56

**DOC—BIS**

**13. Authorization of Certain “Items” to Entities on the Entity List in the Context of Specific Standards Activities**

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Legal Authority:** 50 U.S.C. 4801 to 4852; 50 U.S.C. 4601 et seq.; 50 U.S.C. 1701 et seq.; E.O. 12938

**CFR Citation:** 15 CFR 734.

**Legal Deadline:** None.

**Abstract:** The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to clarify the applicability of the Export Administration Regulations (EAR) to releases of technology for standards setting or development in standards organizations.

**Statement of Need:** The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to clarify the applicability of the Export Administration Regulations (EAR) to releases of technology for standards setting or development in support of U.S. participation in standards efforts.

**Summary of Legal Basis:** There are a variety of legal authorities under which BIS operates. However, ECRA (50 U.S.C. 4817) provides the most substantive legal basis for BIS’s actions under this rule.

**Alternatives:** There are no alternatives to this rule.

**Anticipated Cost and Benefits:** The anticipated costs and benefits of this proposed rule are not applicable.

**Risks:** There are no applicable risks to this rule.

**Timetable:**

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**DOC—BIS**

**14. Commerce Control List: Expansion of Controls on Certain Biological Equipment “Software”**

**Priority:** Other Significant.


**CFR Citation:** 15 CFR 774.

**Legal Deadline:** None.

**Abstract:** BIS is publishing this final rule to amend the Commerce Control List (CCL) by adding a new Export Control Classification Number (ECCN) 2D352 to control “software” that is designed for automated nucleic acid assemblers and synthesizers controlled under ECCN 2B352 and is capable of designing and building functional genetic elements from digital sequence data. These proposed amendments are used to clarify the applicability of the Export Administration Regulations (EAR) to releases of technology for standards setting or development in support of U.S. participation in standards efforts.

**Summary of Legal Basis:** There are a variety of legal authorities under which BIS operates. However, ECRA (50 U.S.C. 4817) provides the most substantive legal basis for BIS’s actions under this rule.

**Alternatives:** The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the Section 1758 process. In so doing, the Secretary must consider the potential end-uses and end-users of emerging and foundational technologies, and the countries to which exports from the United States are restricted (e.g., embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum, a license must be required for the export of such technologies to countries subject to a U.S. embargo.

Prior to the addition of nucleic acid assembler/synthesizer software to the AG biological equipment list, BIS identified this software as a technology to be evaluated as an emerging technology, consistent with the interagency process described in section 1758 of the Export Control Reform Act of 2018 (ECRA) (codified at 50 U.S.C. 4817). This identification was based on a finding that this software is capable of being used to operate nucleic acid assemblers and synthesizers controlled under ECCN 2B352 for the purpose of generating pathogens and toxins without the need to acquire controlled genetic elements and organisms. Consequently, the absence of export controls on this software could be exploited for biological weapons purposes.

**Summary of Legal Basis:** Section 1758(a) of the Export Control Reform Act (ECRA) of 2018 (50 U.S.C. 4817(a)) outlines an interagency process for identifying emerging and foundational technologies. Nucleic acid synthesizer software has been identified as a technology for evaluation as a potential emerging technology, consistent with the interagency process described in section 1758 of ECRA. Consequently, BIS published a proposed rule on November 6, 2020 (85 FR 71012), to provide the public with notice and the opportunity to comment on adding a new ECCN 2D352 to control software for the operation of nucleic acid assemblers and synthesizers described in ECCN 2B352 that is capable of designing and building functional genetic elements from digital sequence data. Subsequent to the publication of this proposed rule, the Australia Group (AG) added this software to their biological equipment Common Control List. This final rule amends the EAR to reflect the action taken by the AG.

**Alternatives:** The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the Section 1758 process. In so doing, the Secretary must consider the potential end-uses and end-users of emerging and foundational technologies, and the countries to which exports from the United States are restricted (e.g., embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum, a license must be required for the export of such technologies to countries subject to a U.S. embargo.
including those countries subject to an arms embargo.

If the interagency process results in a determination that a certain technology constitutes an emerging technology, for purposes of section 1758 of ECRA, then BIS is required, pursuant to ECRA, to institute export controls on such technology. However, BIS does have some flexibility to ensure that the scope of any controls that may be imposed on this technology would be effective (in terms of protecting U.S. national security interests) and appropriate (with respect to minimizing their potential impact on legitimate commercial or scientific applications). In this particular instance, the controls on this technology will be multilateral, because they have been adopted by the Australia Group (AG) for inclusion in their biological equipment Common Control List.

Anticipated Cost and Benefits: The changes that would be made by this rule would only marginally affect the scope of the EAR controls on chemical weapons precursors, human and animal pathogens/toxins, and equipment capable of use in handling biological materials.

The number of additional license applications that would have to be submitted per year, as a result of the addition of ECCN 2D352 to the CCL, as described above, is not expected to exceed fifteen license applications. This total represents a relatively insignificant portion of the overall trade in such items and is well within the scope of the information collection approved by the Office of Management and Budget (OMB) under control number 06940088.

Risks: This software is capable of being used to operate nucleic acid assemblers and synthesizers controlled under ECCN 2B352 for the purpose of generating pathogens and toxins without the need to acquire controlled genetic elements and organisms. Consequently, the absence of export controls on this software could be exploited for biological weapons purposes.

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Regulatory Flexibility Analysis

Required: Undetermined.

Government Levels Affected: None.

Agency Contact: Willard Fisher, Export Administration Specialist, Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230, Phone: 202 482–2440, Fax: 202 482–3355, Email: willard.fisher@bis.doc.gov.

RIN: 0694–A108

DOC—PATENT AND TRADEMARK OFFICE (PTO)

Final Rule Stage

15. Changes To Implement Provisions of the Trademark Modernization Act of 2020

Priority: Other Significant.


CFR Citation: 37 CFR 2; 37 CFR 7.


Abstract: The United States Patent and Trademark Office (USPTO or Office) amends the rules of practice in trademark cases to implement provisions of the Trademark Modernization Act of 2020. The rule establishes ex parte expungement and reexamination proceedings for cancellation of a registration when the required use in commerce of the registered mark has not been made; provides for a new nonuse ground for cancellation before the Trademark Trial and Appeal Board; establishes flexible Office action response periods; and amends the existing letter-of-protest procedure to indicate that letter-of-protest determinations are final and non-reviewable. The USPTO also sets fees for petitions requesting institution of ex parte expungement and reexamination proceedings, and for requests to extend Office action response deadlines. Amendments are also for the rules concerning the suspension of USPTO proceedings and the rules governing attorney recognition in trademark matters. Finally, a new rule is to address procedures regarding court orders cancelling or affecting registrations.

Statement of Need: The purpose of this action is to amend the rules of practice in trademark cases to implement provisions of the Trademark Modernization Act of 2020. In addition, amendments are also proposed for the rules concerning suspension of USPTO proceedings and the rules governing attorney recognition in trademark matters, and a new rule is proposed to address procedures regarding court orders cancelling or affecting registrations.

Summary of Legal Basis: The Trademark Modernization Act of 2020 (TMA) was enacted on December 27, 2020. See Public Law 116260, Div. Q, Tit. II, Subtit. B, 221228 (Dec. 27, 2020). The TMA amends the Trademark Act of 1946 (the Act) to establish new ex parte expungement and reexamination proceedings to cancel, either in whole or in part, registered marks for which the required use in commerce was not made. Furthermore, the TMA amends 14 of the Act to allow a party to allege that a mark has never been used in commerce as a basis for cancellation before the Trademark Trial and Appeal Board (TTAB). The TMA also authorizes the USPTO to promulgate regulations to set flexible Office action response periods between 60 days and 6 months, with an option for applicants to extend the deadline up to a maximum of 6 months from the Office action issue date. In addition, the TMA includes statutory authority for the USPTO’s letter-of-protest procedures, which may allow third parties to submit evidence to the USPTO relevant to a trademark’s registrability during the initial examination of the trademark application, and provides that the decision whether to include such evidence in the application record is final and non-reviewable. The TMA requires the USPTO to promulgate regulations to implement the provisions relating to the new ex parte expungement and reexamination proceedings, and the letter-of-protest procedures, within one year of the TMA’s enactment. The USPTO also proposes under its authority under the Trademark Act of 1946, 15 U.S.C. 1051 et seq., to amend the rules regarding attorney recognition and correspondence, and to add a new rule formalizing the USPTO’s longstanding procedures concerning action on court orders cancelling or affecting a registration under section 37 of the Act, 15 U.S.C. 1119.

Alternatives: The TMA mandates the framework for many of the procedures in this rulemaking, particularly in regard to the changes to the letter-of-protest procedures and most of the procedures for the new ex parte expungement and reexamination proceedings, except for those indicated below. Thus, the USPTO has little to no discretion in the rulemaking required to implement those procedures. For those provisions for which alternatives were possible because the TMA provided the Director discretion to implement regulations (i.e., fees; limit on petitions requesting expungement or...
reexamination; reasonable investigation and evidence; director-initiated proceedings; response time periods in new ex parte proceedings; flexible response periods; suspension of proceedings; and attorney recognition), a full discussion of alternatives is provided in the proposed rule.

Anticipated Cost and Benefits: The proposed regulations have qualitative benefits of ensuring a well-functioning trademark system where the trademark register accurately reflects trademarks that are currently in use.

Risks: The risk of taking no action is that USPTO would not comply with its statutory mandate under the TMA.

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Regulatory Flexibility Analysis
Required: Yes.
Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations.
Government Levels Affected: None.
Agency Contact: Catherine Cain.

TradeMark Manual of Examining Procedure Editor, Department of Commerce, Patent and Trademark Office, P.O. Box 1451, Alexandria, VA 22313, Phone: 571 272–8946, Fax: 751 273–8946, Email: catherine.cain@uspto.gov.

RIN: 0651–AD55
BILLING CODE 3410–12–P

DEPARTMENT OF DEFENSE
Statement of Regulatory Priorities
Background
The Department of Defense (DoD) is the largest Federal department, employing over 1.6 million military personnel and 750,000 civilians with operations all over the world. DoD’s enduring mission is to provide combat-credible military forces needed to deter war and protect the security of our nation. In support of this mission, DoD adheres to a strategy where a more lethal force, strong alliances and partnerships, American technological innovation, and a culture of performance will generate a decisive and sustained United States military advantage. Because of this expansive and diversified mission and reach, DoD regulations can address a broad range of matters and have an impact on varied members of the public, as well as other federal agencies.

Pursuant to Executive Order 12866, “Regulatory Planning and Review” (September 30, 1993) and Executive Order 13563, “Improving Regulation and Regulatory Review” (January 18, 2011), the DoD Regulatory Plan and Agenda provide notice about the DoD’s regulatory and deregulatory actions within the Executive Branch.

Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (January 18, 2011), the Department continues to review existing regulations with a goal to eliminate outdated, unnecessary, or ineffective regulations; account for the currency and legitimacy of each of the Department’s regulations; and ultimately reduce regulatory burden and costs.

DOD Priority Regulatory Actions

The regulatory and deregulatory actions identified in this Regulatory Plan embody the core of DoD’s regulatory priorities for Fiscal Year (FY) 2022 and help support President Biden’s regulatory priorities and the Secretary of Defense’s top priorities, along with those of the National Defense Strategy, to defend the Nation. The DoD prioritization is focused on initiatives that:

• Promote the country’s economic resilience, including addressing COVID-related issues.
• Support underserved communities and improve small business opportunities.
• Promote diversity, equity, inclusion, and accessibility in the Federal workforce.
• Support national security efforts, especially safeguarding Federal Government information and information technology systems.
• Support the climate change emergency; and
• Promote Access to Voting.

Rules That Promote the Country’s Economic Resilience

Pandemic


TRICARE continues to reimburse like Medicare, to the extent practicable, as required by statute. The Department is researching the impacts of making some of those modifications permanent and may pursue such future action.

These modifications include:

• TRICARE Coverages and Payment for Certain Services in Response to the COVID–19 Pandemic. RIN 0720–AB81

DoD is finalizing an interim final rule that temporarily amended 32 CFR part 199 to revise: (1) 32 CFR part 199.4 to remove the restriction on audio-only telemedicine services; (2) 32 CFR part 199.6 to authorize reimbursement for interstate practice by TRICARE-authorized providers when such authority is consistent with State and Federal licensing requirements; and (3) 32 CFR part 199.17 to eliminate copayments for telemedicine services. These changes reduce the spread of COVID–19 among TRICARE beneficiaries by incentivizing use of telemedicine services, and aid providers in caring for TRICARE beneficiaries by temporarily waiving some licensure requirements. The final rule adopts this interim final rule as final with changes.

• TRICARE Coverage of Certain Medical Benefits in Response to the COVID–19 Pandemic. RIN 0720–AB82

DoD is finalizing an interim final rule that temporarily amended 32 CFR part 199 to revise certain elements of the TRICARE program under 32 CFR part 199 to: (1) Waive the three-day prior hospital qualifying stay requirement for coverage of skilled nursing facility care; (2) add coverage for treatment use of investigational drugs under expanded access authorized by the United States (U.S.) Food and Drug Administration (FDA) when for the treatment of coronavirus disease 2019 (COVID–19); (3) waive certain provisions for acute care hospitals that permitted authorization of temporary hospital facilities and freestanding ambulatory surgical centers providing inpatient and outpatient hospital services; and, consistent with similar changes under the Centers for Medicaid and Medicare Services; (4) revise diagnosis related groups (DRG) reimbursement by temporarily reimbursing DRGs at a 20 percent higher rate for COVID–19.
The final rule adopts the interim final rule with changes, except for the note to section 199.4(e)(15)(ii)(A), published at 85 FR 54923, September 3, 2020, which remains interim.

- TRICARE Coverage of National Institute of Allergy and Infectious Disease—Coronavirus Disease 2019 Clinical Trials. RIN 0720–AB83

This interim final rule temporarily amended section 199.4(e)(26) of 32 CFR 199 to revise certain elements of the TRICARE program to add coverage for National Institute of Allergy and Infectious Disease-sponsored clinical trials for the treatment or prevention of coronavirus disease 2019 (COVID–19).

This interim final rule will temporarily amend the TRICARE regulation at 32 CFR part 199 by: (1) Adding freestanding End Stage Renal Disease facilities as a category of TRICARE-authorized institutional provider and modifying the reimbursement for such facilities; (2) adding coronavirus 2019 (COVID–19) Immunizers who are not otherwise an eligible TRICARE-authorized provider as providers eligible for reimbursement for COVID–19 vaccines and vaccine administration; (3) and adopting Medicare New COVID–19 Treatments Add-on Payments (NTCAPs).


This rule seeks to preserve a waiver that allows waivable requirements for the cost-sharing care related to TRICARE-eligible patients who participate in Phase I, II, III, or IV clinical trials examining the treatment or prevention of COVID–19 that are sponsored by NIAID, enforcing the provisions within the agreement between DoD and NIAID. This change establishes requirements for TRICARE cost-sharing care related to NIAID-sponsored COVID–19 clinical trials; these new requirements mirror the existing requirements set forth in 32 CFR 199.4(e)(26)(i)(B) for coverage of cancer clinical trials. This amendment supports statutory intent by encouraging participation of TRICARE beneficiaries in clinical trials studying the prevention or treatment of COVID–19 and contributing to the development of treatments, including vaccines, for COVID–19.

- Expanding TRICARE Access to Care in Response to the COVID–19 Pandemic. RIN 0720–AB85

This interim final rule will temporarily amend the TRICARE regulation at 32 CFR part 199 by: (1) Adding freestanding End Stage Renal Disease facilities as a category of TRICARE-authorized institutional provider and modifying the reimbursement for such facilities; (2) adding coronavirus 2019 (COVID–19) Immunizers who are not otherwise an eligible TRICARE-authorized provider as providers eligible for reimbursement for COVID–19 vaccines and vaccine administration; (3) and adopting Medicare New COVID–19 Treatments Add-on Payments (NTCAPs).


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This rule seeks to preserve a waiver that allows waivable requirements for the cost-sharing care related to TRICARE-eligible patients who participate in Phase I, II, III, or IV clinical trials examining the treatment or prevention of COVID–19 that are sponsored by NIAID, enforcing the provisions within the agreement between DoD and NIAID. This change establishes requirements for TRICARE cost-sharing care related to NIAID-sponsored COVID–19 clinical trials; these new requirements mirror the existing requirements set forth in 32 CFR 199.4(e)(26)(i)(B) for coverage of cancer clinical trials. This amendment supports statutory intent by encouraging participation of TRICARE beneficiaries in clinical trials studying the prevention or treatment of COVID–19 and contributing to the development of treatments, including vaccines, for COVID–19.
be eligible for certain credits and reimbursements. Per the statute, this rule also establishes additional performance goals and outcome-based metrics to measure progress in meeting those goals.

**Rules That Promote Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce**

Nondiscrimination on the Basis of Disability in Program or Activities Assisted or Conducted by the DoD and in Equal Access to Information and Communication Technology Used by DoD, and Procedures for Resolving Complaints. RIN: 0790–AJ04

Revisions to this regulation: (1) Updated and clarify the obligations that Section 504 of the Rehabilitation Act of 1973 (section 504) imposes on recipients of Federal financial assistance and the Military Departments and Components (DoD Components); (2) reflect the most current Federal statutes and regulations, as well as developments in Supreme Court jurisprudence, regarding unlawful discrimination on the basis of disability and promotes consistency with comparable provisions implementing title II of the Americans with Disabilities Act (ADA); (3) implement section 508 of the Rehabilitation Act of 1973 (section 508), requiring DoD make its electronic and information technology accessible to individuals with disabilities; (4) establish and clarify obligations under the Architectural Barriers Act of 1968 (ABA), which requires that DoD make facilities accessible to individuals with disabilities; and (5) Provide complaint resolution and enforcement procedures pursuant to section 504 and the complaint resolution and enforcement procedures pursuant to section 508. These revisions are particularly relevant in light of Executive Order 14035, “Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce.

**Rules That Support National Security Efforts**

Department of Defense (DoD)—Defense Industrial Base (DIB) Cybersecurity (CS) Activities. RIN: 0790–AK86

This rule will amend the DoD—Defense Industrial Base (DIB) Cybersecurity (CS) activities regulation. It will allow a broader community of defense contractors access to relevant cyber threat information that is critical in defending unclassified networks and information systems and protecting DoD warfighting capabilities. These amendments seek to address the increasing cyber threat targeting all defense contractors including those in the vulnerable supply chain by expanding eligibility to defense contractors that process, store, develop, or transmit DoD Controlled Unclassified Information (CUI). These steps align with the Administration’s efforts to provide defense contractors with critical and real-time cybersecurity resources needed to safeguard DoD CUI.

**Rules That Support the Climate Change Emergency**


Where a party other than the USACE seeks to use or alter a Civil Works project that USACE constructed, the proposed use or alteration is subject to the prior approval of the USACE. Some examples of such alterations include an improvement to the project; relocation of part of the project; or installing utilities or other non-project features. This requirement was established in section 14 of the Rivers and Harbors Act of 1899 and is codified at 33 U.S.C. 408 (section 408). Section 408 provides that the USACE may grant permission for another party to alter a Civil Works project, upon a determination that the alteration proposed will not be injurious to the public interest and will not impair the usefulness of the Civil Works project. The USACE is proposing to convert its policy that governs the section 408 program to a binding regulation. This policy, Engineer Circular 1165–2–220, Policy and Procedural Guidance for Processing Requests to Alter U.S. Army Corps of Engineers Civil Works Projects Pursuant to 33 U.S.C. 408, was issued in September 2018.

Credit Assistance for Water Resources Infrastructure Projects. RIN: 0710–AB31

The USACE proposes to implement a new credit program for dam safety work at non-Federal dams. The program is authorized under the Water Infrastructure Finance and Innovation Act of 2014 (WIFIA) and Division D, Title 1 of the Consolidated Appropriations Act of 2021. WIFIA authorizes the USACE to provide secured (direct) loans and loan guarantees (Federal Credit instruments) to eligible water resources infrastructure projects and to charge fees to recover all or a portion of the USACE’ cost of providing credit assistance and the costs of conducting engineering reviews and retaining expert firms, including financial and legal services, to assist in the underwriting and servicing of Federal credit instruments. Projects would be evaluated and selected by the Secretary of the Army (the Secretary), based on the requirements and the criteria described in this rule.

**Flood Control Cost-Sharing Requirements Under the Ability To Pay Provision. RIN: 0710–AB34**

Section 103(m) of the Water Resources Development Act (WRDA) of 1986, as amended (33 U.S.C. 2213(m)), authorizes the USACE to reduce the non-Federal share of the cost of a study or project for certain communities that are not able financially to afford the standard cost-share. Part 241 of title 33 in the Code of Federal Regulations provides the criteria that the USACE uses in making these determinations where the primary purpose of the study or project is flood damage reduction. The proposed rule would update this regulation, including by broadening the project purposes for which the USACE could reduce the non-Federal cost-share on this basis.

Revised Definition of “Waters of the United States”—Rule 1. RIN: 0710–AB40

In April 2020, the EPA, and the Department of the Army (“the agencies”) published the Navigable Waters Protection Rule (NWPR) that revised the previously codified definition of “waters of the United States” (65 FR 22250, April 21, 2020). The agencies are now initiating this new rulemaking process that restores the regulations (51 FR 41206) in place prior to the 2015 “Clean Water Rule: Definition of ‘Waters of the United States’” (80 FR 37054, June 29, 2015), updated to be consistent with relevant Supreme Court decisions. The agencies intend to consider further revisions in a second rule in light of additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pro-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

Revised Definition of “Waters of the United States”—Rule 2. RIN: 0710–AB47

The Department of the Army and the Environmental Protection Agency intend to pursue a second rule defining “Waters of the United States” to consider further revisions to the agencies’ first rule (RIN 0710–AB40) which proposes to restore the regulations in place prior to the 2015 “Clean Water Rule: Definition of ‘Waters
of the United States’” (80 FR 37054, June 29, 2015), updated to be consistent with relevant Supreme Court Decisions. This second rule proposes to include revisions reflecting on additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

Rules Promoting Access to Voting

Federal Voting Assistant Program (FVAP). RN: 0790–AK90

DOD is finalizing an interim final rule for its Federal Voting Assistance Program (FVAP). The FVAP assists overseas service members and other overseas citizens with exercising their voting rights by serving as a critical resource to successfully register to vote. On March 7, 2021, the White House released Executive Order 14019 on Promoting Access to Voting. The purpose of the Executive Order is to protect and promote the exercise of the right to vote, eliminate discrimination and other barriers to voting, expand access to voter registration and accurate election information, and ensure registering to vote and the act of voting be made simple and easy for all those eligible to do so. To accomplish this purpose, with this final rule DoD is doing the following:

• Maximizing voter awareness of Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA) eligibility and resources by providing better coordination with the Federal Government’s voting assistance services to improve voter accessibility and communication.
• Requiring DoD components to establish component-wide programs to communicate and disseminate voting information, with the goal of improving communication and clarity for the impacted population.
• Requiring federal agencies to enter into memorandums of understanding (MOU) with the DoD to provide accurate, nonpartisan voting information and assistance to ensure military and overseas voters understand their voting rights, how to register and apply for an absentee ballot, and how to return their absentee ballot successfully.
• Promoting opportunities to register to vote and participate in elections to include civilians working for the Department who vote locally.

DOD—OFFICE OF THE SECRETARY (OS)

Proposed Rule Stage


Priority: Other Significant.

CFR Citation: 32 CFR 236.
Legal Deadline: None.

Abstract: The DIB CS Program is currently only permitted to provide cyber threat information to cleared defense contractors, per the Program eligibility requirements within 32 CFR part 236. However, this proposed revision to the Federal rule would allow all defense contractors who process, store, develop, or transit DoD CUI to be eligible to participate and begin receiving critical cyber threat information. Expanding participation in the DIB CS Program is part of DoD’s comprehensive approach to collaborate with the DIB to counter cyber threats through information sharing between the Government and DIB participants. The expanded eligibility criteria will allow a broader community of defense contractors to participate in the DIB CS Program, in alignment with the National Defense Strategy.

Statement of Need: Unauthorized access and compromise of DoD unclassified information and operations poses an imminent threat to U.S. national security and economic security interests. Defense contractors with this information are being targeted on a daily basis. Many of these contractors are small and medium size contractors that can benefit from partnering with DoD to enhance and supplement their cybersecurity capabilities.

Summary of Legal Basis: This revised regulation supports the Administration’s effort to promote public-private cyber collaboration by expanding eligibility for the DIB CS voluntary cyber threat information sharing program to all defense contractors. This regulation aligns with DoD’s statutory responsibilities for cybersecurity engagement with those contractors supporting the Department.

Alternatives: (1) No action alternative: Maintain status quo with the ongoing voluntary cybersecurity program for cleared contractors. (2) Next best alternative: DoD posts generic cyber threat information and cybersecurity best practices on a public accessible website without directly engaging participating companies.

Anticipated Cost and Benefits: Participation in the voluntary DIB CS
Program enables DoD contractors to access Government Furnished Information and collaborate with the DoD Cyber Crime Center (DC3) to better respond to and mitigate the cyber threat. To participate in the DIB CS Program, DoD contractors must have or obtain a DoD-approved, medium assurance certificate to enable access to a secure DoD unclassified web portal. Cost of the DoD-approved medium assurance certificate is approximately $175 for each individual identified by the DoD contractor. See https://public.cyber.mil/eca/ for more information about DoD-approved certificates.

Contractors are encouraged to voluntarily 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 cyber threat actor activity. This cyber information may be of interest to the DIB and DoD for situational awareness and does not include mandatory cyber incident reporting included under DFARS 252.204–7012.

The costs are under review. Risks: Cyber threats to DIB unclassified information systems represent an unacceptable risk of compromise of DoD information and mission and pose an imminent threat to U.S. national security and economic security interests. This threat is particularly acute for those small and medium size companies with less mature cybersecurity capabilities. The combination of mandatory cyber activities under DFARS 252.204–7012, combined with the voluntary participation in the DIB CS Program, will enhance and supplement DoD contractors capabilities to safeguard DoD information that resides on, or transits, DoD contractors unclassified network or information systems. Through collaboration with DoD and the sharing with other contractors in the DIB CS Program, defense contractors will be better prepared to mitigate the cyber risk they face today and in the future.

Timetable:

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Regulatory Flexibility Analysis Required: No.
Small Entities Affected: No.
Agency Contact: Kevin Dulany, Director, Cybersecurity Policy and Partnerships CIO, Department of Defense, Office of the Secretary, 4800 Mark Center, Alexandria, VA 22311, Phone: 571-372-4699, Email: kevin.m.dulany.civ@mail.mil. RIN: 0790-ÅK86

DOD—OS
Final Rule Stage

17. Nondiscrimination on the Basis of Disability in Programs or Activities Assisted or Conducted by the DoD

Priority: Other Significant.
CFR Citation: 32 CFR 56.
Legal Deadline: None.
Abstract: The Department of Defense (DoD) is amending its regulation prohibiting unlawful discrimination on the basis of disability in programs or activities receiving Federal financial assistance from, or conducted by, DoD. These revisions will update and clarify the obligations that section 504 of the Rehabilitation Act of 1973, as amended, imposes on recipients of Federal financial assistance and DoD Components, and the obligations that the Architectural Barriers Act imposes on DoD Components. The updates will also clarify the procedures for resolving complaints regarding information and communication technology accessible to and usable by individuals with disabilities in accordance with section 508 of the Rehabilitation Act, as amended. This rule promotes the Biden Administration’s priorities on diversity, equity, and inclusion.

Statement of Need: Finalization of this Department-wide rule will clarify the longstanding policy of the Department. It does not change the Department’s practices in addressing issues of discrimination. This rule amends the Department’s prior regulation to include updated accessibility standards for recipients of Federal financial assistance to be more user-friendly and to support individuals with disabilities. This update is particularly relevant in light of Executive Order 14035, Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce.

Summary of Legal Basis: This rule is proposed under the authorities of title 29, U.S.C., chapter 16, subchapter V, sections 794 through 794d, codifying legislation prohibiting discrimination on the basis of disability under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Federal agency or any provision establishing the United States Access Board and requiring Federal agencies to ensure that information and communication technology is accessible to and usable by individuals with disabilities. Title 28, Code of Federal Regulations, part 41 implementing Executive Order 12250, which assigns the DOJ responsibility to coordinate implementation of section 504 of the Rehabilitation Act.

Alternatives: The Department considered taking no new action and continuing to rely on the existing regulation. The Department considered issuing sub-regulatory guidance to clarify existing regulation. Both options were rejected because of the need to update and clarify the Department’s obligations pursuant to section 504 and section 508 of the Rehabilitation Act of 1973, as amended.

Anticipated Cost and Benefits: Because OMB originally determined this rule to not be a significant regulatory action, a cost and benefit analysis has not yet been completed.

Risks: Without this final rule, the Department’s current regulation is inconsistent with current Federal statutes and regulations, as well as developments in Supreme Court jurisprudence, regarding unlawful discrimination on the basis of disability. Consistent with congressional intent, the provisions in the final rule are consistent with the nondiscrimination provisions in DOJ regulations implementing title II of the ADA Amendments Act (applicable to state and local government entities).

Timetable:

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Regulatory Flexibility Analysis Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Additional Information: The full title of the rule is “Nondiscrimination on the Basis of Disability in Programs or Activities Assisted or Conducted by the DoD and in Equal Access to Information and Communication Technology Used by DoD, and Procedures for Resolving Complaints.” That title is too long to include above, so I am including it here.
DoD Instruction 1020.dd (“Unlawful Discrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance from, or Conducted by, the DoD”) will be codified as a rule in the next major revision of DoD instruction 5034 Federal Register.
Agency Contact: Randy Cooper, Director, Department of Defense Disability EEO Policy and Compliance, Department of Defense, Office of the Secretary, 4000 Defense Pentagon, Room 5D641, Washington, DC 20301–4000, Phone: 703 571–9327, Email: randy.d.cooper3.civ@mail.mil.
RIN: 0790–AJ04

DOD—OS

18. Federal Voting Assistance Program

Priority: Other Significant.
CFR Citation: 32 CFR 233.
Legal Deadline: None.
Abstract: The FVAP assists overseas service members and other overseas citizens with exercising their voting rights by serving as a critical resource to successfully register to vote. It requires Federal agencies to enter into Memorandums of Understanding with the DoD to provide accurate, nonpartisan voting information and assistance to ensure military and overseas voters understand their voting rights, how to register and apply for an absentee ballot, and how to return their absentee ballot successfully.

Statement of Need: This rule establishes policy and assigns responsibilities for the Federal Voting Assistance Program (FVAP). It establishes policy and assigns responsibilities for the development and implementation of installation voter assistance (IVA) offices as voter registration agencies. This part establishes policy to develop and implement, jointly with States, procedures for persons to apply to register to vote at recruitment offices of the Military Services.

Summary of Legal Basis: This rule is proposed under the authorities of the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), 52 U.S.C. chapter 203, on behalf of the Secretary of Defense, as the Presidential designee under 53 U.S.C. 20301(a). See Executive Order No. 12642, Designation of Secretary of Defense as Presidential Designee, 53 FR 21975 (June 8, 1988) and Executive Order 14019, Promoting Access to Voting.

Alternatives: No Action—If DoD took no action, decreases in successful voting by voters covered by the Uniformed and Overseas Citizens Absentee Voting Act could occur.

Voters who received assistance from FVAP or Voting Assistance Officers were significantly more likely to submit a ballot than if they did not receive that assistance a consistent finding across the last four General Elections. The impacted public, without coordinated FVAP voter assistance, could experience confusion with the voting registration process, and may endure inefficient FVAP assistance leading up to, and on Election Day. With no purposeful effort to streamline these regulations, there is a dire possibility that absentee voter ballots will not be sent and received in time to be counted. DoD, as the presidential designee agency, pursuant to Executive Order 12642, shoulders the responsibility and desire to resolve known issues, better communicate with the public, and provide a seamless and uniform voting assistance framework for the public populations overseas.

Anticipated Cost and Benefits: This amendment of the current policies seeks to establish uniform framework within DoD on how to interact and disseminate communications with the impacted public populations overseas. The changes outlined in this rule improve the transparency and effectiveness of communication to the general public, absent overseas voters, Service member spouse and dependents, and eligible voters who seek to register to vote on Military Service installations. This includes maximizing awareness of voter UOCAVA eligibility, and providing resources to the impacted public populations. These changes will maximize voting assistance effectiveness and outcomes, address known concerns impacting the public, ahead of upcoming election cycles.

While the Department estimates that the public will not incur any costs as a result of this rule, the public may receive better voter assistance since DoD will improve the Government’s coordination to provide voter assistance to absent uniformed service voters and overseas voters and support the government’s efforts to implement a comprehensive program to cover all executive branch agencies and overseas citizens more broadly.

Risks: This rule seeks to increase the likelihood of voters protected under UOCAVA and military voting assistance laws to receive and return absentee ballots. It enables FVAP to provide assistance and information to military and overseas American voters in an effective manner based on surveys, research and historical after action reports.

Should FVAP become unable to foster voter awareness through the States and voter assistance programs, the Department of Defense will become less effective to meet military and civilian voter assistance requirements, thus increasing the possible risk of absentee ballot rejections during federal election cycles. This may bring unwanted stakeholder and Congressional scrutiny. FVAP would cease to provide active engagement mechanisms to elicit input and offer recommendations to improve levels of voter success and effectiveness for State absentee balloting processes for absent overseas uniformed voters and citizens.

Timetable:

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Regulatory Flexibility Analysis

Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Agency Contact: David Beirne, Director, DOD/HRA FVAP, Department of Defense, Office of the Secretary, 48 Mark Center Drive, Alexandria, VA 22408, Phone: 571 372–0740, Email: david.e.beirne.civ@mail.mil.
RIN: 0790–AK90

DOD—DEFENSE ACQUISITION
REGULATIONS COUNCIL (DARC)

Proposed Rule Stage


Priority: Other Significant.
Legal Authority: 41 U.S.C. 1303
CFR Citation: 48 CFR 227; 48 CFR 252.
Legal Deadline: None.
Abstract: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement changes related to data rights in the Small Business Administration’s Policy Directive for the Small Business Innovation Research (SBIR) Program, published in the Federal Register on April 2, 2019 (84 FR 12794). The final SBA Policy Directive includes several revisions to clarify data rights, which require corresponding revisions to the DFARS.

Statement of Need: This rule is necessary to implement the Small Business Administration (SBA) related to data rights in the Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program Policy Directive, published in the Federal
DOD—DARC

20. Reauthorization and Improvement of Mentor-Protege Program (DFARS Case 2020–D009)


Statement of Need: This rule is necessary to amend the DFARS to implement the reauthorization of and amendments to the Mentor Protégé Program provided by section 872 of the National Defense authorization act (NDAA) of Fiscal Year (FY) 2020.

Summary of Legal Basis: The legal basis for this rule is section 872 of the NDAA for FY 2020 (Pub. L. 116–92).

Risks: There are no alternatives that would meet the stated objective of this rule.

Anticipated Cost and Benefits: While specific costs and savings have not been quantified, this rule is expected to have significant benefit for small businesses participating in the DoD SBIR/STTR program. SBIR and STTR enable small businesses to explore their technological potential and provide the incentive to profit from its commercialization. By including qualified small businesses in the nation’s R&D arena, high-tech innovation is stimulated, and the United States gains entrepreneurial spirit as it meets its specific research and development needs.

Alternatives: There are no alternatives that would meet the stated objective of this rule.

Risks: The continuous protection of an awardee’s SBIR/STTR Data while actively pursuing or commercializing its technology with the Federal Government, provides a significant incentive for innovative small businesses to participate in these programs.

Timetable:

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Regulatory Flexibility Analysis Required: Yes.


Agency Contact: Jennifer Johnson, Defense Acquisition Regulations System, Department of Defense, Defense Acquisition Regulations Council, 3060 Defense Pentagon, Room 3B941, Washington, DC 20301–3060. Phone: 571 372–6100, Email: jennifer.d.johnson1.civ@mail.mil. RIN: 0750–AK84

DOD—DARC

Final Rule Stage


Abstract: DoD is issuing a final rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement Executive Order 13881, Maximizing Use of American-Made Goods, Products, and Materials. Executive Order 13881 requires an amendment to the Federal Acquisition Regulation (FAR) to provide that materials shall be considered of foreign origin if: (a) For iron and steel end products, the cost of foreign iron and steel used in such iron and steel end products constitutes 5 percent or more of the cost of all the products used in such iron and steel end products; or (b) For all other end products, the cost of the foreign products used in such end products constitutes 45 percent or more of the cost of all the products used in such end products. The FAR changes were accomplished under FAR Case 2019–016, published in the Federal Register at 86 FR 6180. This DFARS rule will make conforming changes to the DFARS.

Statement of Need: This rule is needed to implement Executive Order 13881, Maximizing Use of American-Made Goods, Products, and Materials, dated July 15, 2019, which requires an amendment to the Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS) to provide that under the Buy American statute, materials shall be considered of foreign origin if—

(A) For iron and steel products, the cost of foreign iron and steel used in such iron and steel products constitutes 5 percent or more of the cost of all the product’s domestic content; or

(B) For all other products, the cost of the foreign components used in such
products constitutes 45 percent or more of the cost of all the product’s domestic content.

In addition, the Executive order provides that in determining price reasonableness, the evaluation factors of 20 percent (for other than small businesses), or 30 percent (for small businesses) shall be applied to offers of materials of foreign origin. The DFARS applies a 50 percent factor and requires no additional revisions. This rule makes conforming changes to the applicable clauses as a result of implementation of the Executive order requirements in the FAR.


Alternatives: There are no alternatives that would meet the requirements of Executive Order 13881.

Anticipated Cost and Benefits: This rule increases the percentages for use in the domestic content test applied to offers of products and materials to determine domestic or foreign origin. The rule will strengthen domestic preferences under the Buy American statute and provide both large and small businesses the opportunity and incentive to deliver U.S. manufactured products from domestic suppliers. It is expected that this rule will benefit large and small U.S. manufacturers, including those of iron or steel.

Risks: N/A.

Timetable:

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<td>08/30/21</td>
<td>86 FR 48370</td>
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<td>10/29/21</td>
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<td>02/00/22</td>
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</tbody>
</table>

Regulatory Flexibility Analysis Required: No.

Small Entities Affected: Businesses.


International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact: Jennifer Johnson, Defense Acquisition Regulations System, Department of Defense, Defense Acquisition Regulations Council, 3060 Defense Pentagon, Room 3B941, Washington, DC 20301–3060, Phone: 571 372–6100, Email: jennifer.d.johnson1.civ@mail.mil.

RIN: 0750–AK85

DOD—U.S. ARMY CORPS OF ENGINEERS (COE)

Proposed Rule Stage

22. Policy and Procedures for Processing Requests To Alter U.S. Army Corps of Engineers Civil Works Projects Pursuant to 33 U.S.C. 408

Priority: Other Significant.

Legal Authority: 33 U.S.C. 408

CFR Citation: 33 CFR 350.

Legal Deadline: None.

Abstract: Where a party other than the U.S. Army Corps of Engineers (Corps) seeks to use or alter a Civil Works project that the Corps constructed, the proposed use or alteration is subject to the prior approval of the Corps. Some examples of such alterations include an improvement to the project; relocation of part of the project; or installing utilities or other non-project features. This requirement was established in section 14 of the Rivers and Harbors Act of 1899 and is codified at 33 U.S.C. 408 (section 408). Section 408 provides that the Corps may grant permission for another party to alter a Civil Works project upon a determination that the alteration proposed will not be injurious to the public interest and will not impair the usefulness of the Civil Works project. The Corps is proposing to convert its policy that governs the section 408 review process in the form of a binding regulation. The current Corps policy appears in an Engineer Circular that has expired. The next best alternative would involve issuing these requirements in the form of an Engineer Regulation. That alternative would not fulfill the intent of the law because it would not be binding on the regulated public.

Anticipated Cost and Benefits: The proposed rule would reduce costs to the regulated public by clarifying the applicable requirements and providing consistent implementation of these requirements across the Corps program.

Risks: The proposed action is not anticipated to increase risk to public health, safety, or the environment because it outlines the procedures the Corps will follow when evaluating requests for section 408 permissions. The Corps will comply with all statutory requirements when reviewing requests.

Timetable:

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Regulatory Flexibility Analysis Required: No.

Small Entities Affected: None.

Government Levels Affected: None.


DOD—COE

23. Credit Assistance for Water Resources Infrastructure Projects

Priority: Other Significant.

CFR Citation: 33 CFR 386.

Legal Deadline: None.

Abstract: The U.S. Army Corps of Engineers (Corps) proposes to implement a new credit program for dam safety work at non-Federal dams. The program is authorized under the Water Infrastructure Finance and Innovation Act of 2014 (WIFIA) and Division D, title 1 of the Consolidated Appropriations Act of 2020. WIFIA authorizes the Corps to provide secured (direct) loans and loan guarantees (Federal Credit instruments) to eligible water resources infrastructure projects and to charge fees to recover all or a portion of the Corps’ cost of providing credit assistance and the costs of conducting engineering reviews and retaining expert firms, including financial and legal services, to assist in the underwriting and servicing of Federal credit instruments. Projects would be evaluated and selected by the Secretary of the Army (the Secretary) based on the requirements and the criteria described in this rule.

Statement of Need: The U.SACE WIFIA program is focused on providing Federal loans, and potentially to also include loan guarantees, to projects for maintaining, upgrading, and repairing dams identified in the National Inventory of Dams owned by non-federal entities. These loans will be repaid with non-Federal funding.

Summary of Legal Basis: The U.SACE WIFIA program was authorized under Subtitle C of Title V of the Water Resources Reform and Development Act of 2014 (WRRDA 2014), which authorizes USACE to provide secured (direct) loans, and potentially to also include loan guarantees, to eligible water resources infrastructure projects (needed further authorization was provided by Division D, title 1 of the Consolidated Appropriations Act of 2020). The statute also authorizes USACE to charge fees to recover all or a portion of USACE’s cost of providing credit assistance and the costs of conducting engineering reviews and retaining expert firms, including financial and legal services, to assist in the underwriting and servicing of Federal credit instruments.

The Fiscal 2021 Consolidated Appropriations Act, provided USACE WIFIA appropriations of $2.2M admin, and $12M credit subsidy and a loan volume limit of $950M. These appropriated funds are limited to fund projects focused on maintaining, upgrading, and repairing dams identified in the National Inventory of Dams owned by non-federal entities.

Alternatives: The preferred alternative would be to conduct proposed rulemaking to implement a new credit program for dam safety work at non-Federal dams in the form of a binding regulation in compliance with the Water Infrastructure Finance and Innovation Act of 2014 (WIFIA) and Division D, title 1 of the Consolidated Appropriations Act of 2020. The next best alternative would involve issuing these implementing procedures in the form of an Engineer Regulation. That alternative would not fulfill the intent of the law because it would not be binding on the regulated public. The no action alternative would be to not conduct rulemaking which would not fulfill the authorization provided by Congress.

Anticipated Cost and Benefits: The proposed rule would add Corps procedures to the CFR on the implementation of a new credit program for dam safety work at non-Federal dams to allow for consistent implementation across the Corps and clear understanding of the program and its requirements by the regulated public. The USACE would incur costs to administer the loan program while benefits are expected for the public in the form of benefits from projects enabled by WIFIA loans.

Risks: The proposed action is not anticipated to increase risk to public health, safety, or the environment because it outlines the procedures the Corps will follow for implementing a federal loan program. The Corps will comply with all statutory requirements when reviewing requests.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
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<tbody>
<tr>
<td>NPRM</td>
<td>11/00/21</td>
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</table>

Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Agency Contact: Aaron Snyder, Department of Defense, U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 20314, Phone: 651 290–5489, Email: aaron.m.snyder@usace.army.mil.

Related RIN: Merged with 0710–AB32.

RIN: 0710–AB31

DOD—COE

24. Flood Control Cost-Sharing Requirements Under the Ability To Pay Provision


Unfunded Mandates: Undetermined.

Legal Authority: 33 U.S.C. 2213(m)

CFR Citation: 33 CFR 241.

Legal Deadline: None.

Abstract: Section 103(m) of the Water Resources Development Act (WRDA) of 1986, as amended (33 U.S.C. 2213(m)), authorizes the U.S. Army Corps of Engineers (Corps) to reduce the non-Federal share of the cost of a study or project for certain communities that are not able financially to afford the standard non-Federal cost-share. Part 241 of title 33 in the Code of Federal Regulations provides the criteria that the Corps uses in making these determinations where the primary purpose of the study or project is flood damage reduction. The proposed rule would update this regulation, including by broadening its applicability by including projects with other purposes (instead of just flood damage reduction) and by including the feasibility study of a project (instead of just design and construction).

Statement of Need: The Corps may conduct a rulemaking to propose amendments to the Corps’ regulations at 33 CFR part 241 for Corps projects. The WRDA 2000 modified Section 103(m) to also include the following mission areas: Environmental protection and restoration, flood control, navigation, storm damage protection, shoreline erosion, hurricane protection, and recreation or an agricultural water supply project which have not yet been added to the regulation. It also included the opportunity to cost share all phases of a USACE project to also include feasibility in addition to the already covered design and construction. This rule would provide a framework for deciding which projects are eligible for consideration for a reduction in the non-Federal cost share based on ability to pay.


Alternatives: The preferred alternative would be to conduct rulemaking to amend 33 CFR 241 by broadening the project purposes for which the Corps could reduce the non-Federal cost-share based on ability to pay and by allowing such a reduction for feasibility studies. The next best alternative would be to provide additional guidance instead of amending the existing regulation.
alternative could lead to confusion for the regulated public.

**Anticipated Cost and Benefits:** The proposed rule would add Corps procedures on the ability to pay provision allowing for consistent implementation across the Corps and clear understanding of the program and its requirements by the regulated public.

**Risks:** The proposed action is not anticipated to increase risk to public health, safety, or the environment because it outlines the procedures the Corps will follow when evaluating the ability to pay provision for cost-sharing with the non-Federal sponsor.

**Timetable:**

<table>
<thead>
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**Regulatory Flexibility Analysis**

**Required:** Undetermined.

**Government Levels Affected:** None.

**Agency Contact:** Amy Frantz, Program Manager, Department of Defense, U.S. Army Corps of Engineers, CECW–P, 441 G Street NW, Washington, DC 20314, Phone: 202 761–0106, Email: amy.k.frantz@usace.army.mil.

**Related RIN:** Previously reported as 0710–AA91.
**RIN:** 0710–AB34

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**DOD—COE**

25. Revised Definition of “Waters of the United States”—Rule 1

**Priority:** Economically Significant. Major under 5 U.S.C. 801.

**Unfunded Mandates:** Undetermined.

**Legal Authority:** 33 U.S.C. 1344
**CFR Citation:** 33 CFR 328.

**Legal Deadline:** None.

**Abstract:** In April 2020, the EPA and the Department of the Army (“the agencies”) published the Navigable Waters Protection Rule (NWPR) that revised the previously codified definition of “waters of the United States” (85 FR 22250, April 21, 2020). The agencies are now initiating this new rulemaking process that restores the regulations (51 FR 41206) in place prior to the 2015 “Clean Water Rule: Definition of ‘Waters of the United States’ (80 FR 37054, June 29, 2015),” updated to be consistent with relevant Supreme Court decisions. The agencies intend to consider further revisions in a second rule in light of additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

**Statement of Need:** In 2015, the Environmental Protection Agency and the Department of the Army (“the agencies”) published the “Clean Water Rule: Definition of ‘Waters of the United States (80 FR 37054, June 29, 2015).” In April 2020, the agencies published the Navigable Waters Protection Rule (85 FR 22250, April 21, 2020). The agencies conducted a substantive re-evaluation of the definition of “waters of the United States” in accordance with the Executive Order 13990 and determined that they need to revise the definition to ensure the agencies listen to the science, protect the environment, ensure access to clean water, consider how climate change resiliency may be affected by the definition of waters of the United States, and to ensure environmental justice is prioritized in the rulemaking process.

**Summary of Legal Basis:** The Clean Water Act (33 U.S.C. 1251 et seq.). **Alternatives:** Please see EPA’s alternatives. EPA is the lead for this rulemaking action.

**Anticipated Cost and Benefits:** Please see EPA’s statement of anticipated costs and benefits. EPA is the lead for this rulemaking action.

**Risks:** Please see EPA’s risks. EPA is the lead for this rulemaking action.

**Timetable:**

<table>
<thead>
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</table>

**Regulatory Flexibility Analysis**

**Required:** Undetermined.

**Government Levels Affected:** None.

**Agency Contact:** Stacey M. Jensen, Office of the Assistant Secretary of the Army, Department of Defense, U.S. Army Corps of Engineers, 108 Army Pentagon, Washington, DC 22202, Phone: 703 695–6791, Email: stacey.m.jensen.civ@mail.mil.

**Related RIN:** Previously reported as 0710–AB40.
**RIN:** 0710–AB40

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**DOD—COE**

26. ● Revised Definition of “Waters of the United States”—Rule 2 (Reg Plan Seq No. XX)

**Priority:** Economically Significant. Major under 5 U.S.C. 801 is undetermined.

**Unfunded Mandates:** Undetermined.

**Legal Authority:** 33 U.S.C. 1344
**CFR Citation:** 33 CFR 328.

**Legal Deadline:** None.

**Abstract:** The Department of the Army and the Environmental Protection Agency intend to pursue a second rule defining “Waters of the United States” to consider further revisions to the agencies’ first rule (RIN 0710–AB40) which proposes to restore the regulations in place prior to the 2015 waters of the United States rule (51 FR 41206), updated to be consistent with relevant Supreme Court Decisions. This second rule proposes to include revisions reflecting on additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

**Statement of Need:** In 2015, the Environmental Protection Agency and the Department of the Army (“the agencies”) published the “Clean Water Rule: Definition of ‘Waters of the United States’ (80 FR 37054, June 29, 2015).” In April 2020, the agencies published the Navigable Waters Protection Rule (85 FR 22250, April 21, 2020). The agencies conducted a substantive re-evaluation of the definition of “waters of the United States” in accordance with the Executive Order 13990 and determined that they need to revise the definition to ensure the agencies listen to the science, protect the environment, ensure access to clean water, consider how climate change resiliency may be affected by the definition of waters of the United States, and to ensure environmental justice is prioritized in the rulemaking process.

**Summary of Legal Basis:** The Clean Water Act (33 U.S.C. 1251 et seq.). **Alternatives:** Please see EPA’s alternatives. EPA is the lead for this rulemaking action.

**Anticipated Cost and Benefits:** Please see EPA’s statement of anticipated costs and benefits. EPA is the lead for this rulemaking action.

**Risks:** Please see EPA’s risks. EPA is the lead for this rulemaking action.

**Timetable:**

<table>
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**Regulatory Flexibility Analysis**

**Required:** Undetermined.

**Government Levels Affected:** Undetermined.

**Federalism:** Undetermined.

**Agency Contact:** Stacey M. Jensen, Office of the Assistant Secretary of the Army, Department of Defense, U.S. Army Corps of Engineers, 108 Army Pentagon, Washington, DC 22202, Phone: 703 695–6791, Email: stacey.m.jensen.civ@mail.mil.

**Related RIN:** Previously reported as 0710–AB47.
**RIN:** 0710–AB47
SUMMARY OF GOVERNMENT COSTS OF THE PROPOSED COVID–19 TELEHEALTH IFR

<table>
<thead>
<tr>
<th>Government Healthcare Cost (HC)</th>
<th>3-Month scenario</th>
<th>6-Month scenario</th>
<th>9-Month scenario</th>
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<tbody>
<tr>
<td>Loss of copays on existing telehealth</td>
<td>$156,949</td>
<td>$313,897</td>
<td>$470,846</td>
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<tr>
<td>Induced demand</td>
<td>117,772</td>
<td>235,544</td>
<td>353,316</td>
</tr>
<tr>
<td>Loss of copays on in-person shifting to Telehealth</td>
<td>26,673,895</td>
<td>48,611,002</td>
<td>65,459,795</td>
</tr>
<tr>
<td>Subtotal, Government HC cost</td>
<td>26,948,616</td>
<td>49,160,443</td>
<td>66,283,957</td>
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<tr>
<td>Start-up administrative cost</td>
<td>67,494</td>
<td>67,494</td>
<td>67,494</td>
</tr>
<tr>
<td>Total Government Cost increase</td>
<td>27,016,110</td>
<td>49,227,937</td>
<td>66,351,451</td>
</tr>
</tbody>
</table>

Beneficiary Cost Impact

There are two types of savings for beneficiaries estimated here. First, beneficiaries would avoid the cost-sharing they otherwise would have paid on existing telehealth visits and on in-person visits that would shift to telehealth. It is estimated the cost-sharing savings to beneficiaries would be: $26,830,844 for a three-month scenario; $48,924,899 for a six-month scenario; and $65,930,641 for a nine-
An important value to beneficiaries that is not feasible to estimate but worth noting is the possibility that shifting visits from in-person to telehealth might reduce the risk of COVID–19 exposure, with all the potential benefits that could accompany that reduced exposure risk. This reduced risk of COVID–19 exposure may also result in downstream reductions in cost to the TRICARE Program in avoided COVID–19 diagnostics and treatment.

**Risks:** None. This rule will promote the efficient functioning of the economy and markets by temporarily modifying regulations to ensure that actors in the health care market (primarily health care providers) will continue to be reimbursed despite disruption in the health care ecosystem by the COVID–19 pandemic. Reimbursing providers despite changing licensing requirements and in ways that recognize the critical role telehealth will play in the coming months ensures that TRICARE supports not just its beneficiaries, but the economy in general.

**Timetable:**

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</table>

**Regulatory Flexibility Analysis:**

**Required:** No.

**Government Levels Affected:** None.

**Agency Contact:** Erica Ferron, Defense Health Agency, Medical Benefits and Reimbursement Division, Department of Defense, Office of Assistant Secretary for Health Affairs, 16401 E Centretech Parkway, Aurora, CO 80011–9066, Phone: 303 676–3626, Email: erica.c.ferron.civ@mail.mil.

**RIN:** 0720–AB81

**DOD—DODOASHA**

28. Tricare Coverage of Certain Medical Benefits in Response to the Covid–19 Pandemic

**Priority:** Other Significant.

**Legal Authority:** 5 U.S.C. 301; 10 U.S.C. ch. 55

**CFR Citation:** 32 CFR 199.

**Legal Deadline:** None.

**Abstract:** The Department of Defense is finalizing an interim final rule that temporarily amended 32 CFR part 199 to revise certain elements of the TRICARE Program under 32 CFR part 199 to: (1) Waive the three-day prior hospital qualifying stay requirement for coverage of skilled nursing facility care; (2) add coverage for treatment use of investigational drugs under expanded access authorized by the United States (U.S.) Food and Drug Administration (FDA) when for the treatment of coronavirus disease 2019 (COVID–19); (3) waive certain provisions for acute care hospitals that permitted authorization of temporary hospital facilities and freestanding ambulatory surgical centers providing inpatient and outpatient hospital services; and, consistent with similar changes under the Centers for Medicaid and Medicare Services; (4) revise diagnosis related group (DRG) reimbursement by temporarily reimbursing DRGs at a 20 percent higher rate for COVID–19 patients; and (5) waive certain requirements for long term care hospitals. The final action permanently adopts Medicare’s New Technology Add-On Payments (NTAPs) and Hospital Value-Based Purchasing (HVBP) Program. These provisions support increased access to acute care.

The modification to paragraph 199.4(g)(15) permits cost-sharing of investigational new drugs (INDs). This provision also increases access to emerging therapies.

The modifications to paragraph 199.6(b)(4)(i) waives certain provisions for acute care hospitals that will permit authorization of temporary hospital facilities and freestanding ambulatory surgical centers. This provision supports increased access to acute care.

**Summary of Need:** Pursuant to the President’s emergency declaration and as a result of the worldwide coronavirus disease 2019 (COVID–19) pandemic, the Assistant Secretary of Defense for Health Affairs is temporarily modifying the following regulations, but in each case, only to the extent necessary to ensure that TRICARE beneficiaries have access to the most up-to-date care required for the diagnosis and treatment of COVID–19, and that TRICARE continues to reimburse like Medicare, to the extent practicable, as required by statute.

The modification to paragraph 199.4(b)(3)(xiv) waives the requirement for a minimum three-day prior hospital stay, not including leave day, for coverage of a skilled nursing facility admission. This provision reduces stress on acute care hospitals.

The modification to paragraph 199.4(g)(15) permits cost-sharing of investigational new drugs (INDs). This provision also increases access to emerging therapies.

The modification to paragraph 199.6(b)(4)(i) waives certain provisions for acute care hospitals that will permit authorization of temporary hospital facilities and freestanding ambulatory surgical centers. This provision supports increased access to acute care.

The modifications to paragraph 199.14(a)(1)(iii)(E) increase the diagnosis related group (DRG) amount by 20 percent for individual diagnosed with COVID–19 and adopt Medicare’s New Technology Add-On Payments (NTAPs) and Hospital Value-Based Purchasing (HVBP) Program. These provisions support the requirement that TRICARE reimburse like Medicare. The NTAPs and HVBP Program are adopted permanently.

The modification to paragraph 199.14(a)(9) waives site neutral payment provisions by reimbursing all long-term care hospitals (LTCHs) at the standard federal rate for claims. This provision supports the requirement that TRICARE reimburse like Medicare.

**Summary of Legal Basis:** This rule is issued under 10 U.S.C. 1073 (a)(2)
The duration of the COVID–19 national emergency and Health and Human Services Public Health Emergency (PHE) are uncertain, resulting in a range of estimates for each provision in this IFR. Cost estimates are provided for an approximate nine-month (ending 12/31/2020) and eighteen-month scenario (ending 9/30/2021). The nine-month and 18-month periods would be longer for those provisions applicable beginning in January of this year, and shorter for those effective the date this IFR publishes. The terms nine-month and 18-month period are used throughout this estimate for the sake of simplicity. The cost estimates consider whether the outbreak will have more than one active stage. The first active stage is considered to be March through August 2020, based on the Institutes for Health Metrics and Evaluation data as of May 12, 2020 (https://covid19.healthdata.org/united-states-of-america). A two-wave scenario would have a second stage in winter/spring 2021, while a three-wave scenario would have additional waves from September 2020 to December 2020 and from January 2021 to June 2021.

Based on these factors, we estimate that the total cost estimate for this IFR will be between $43.6M and $59.4M for a nine-month period, and $66.3M to $82.1M for an 18-month period. This estimate includes just over $1M in administrative start-up costs and no ongoing administrative costs. The primary cost drivers in this analysis are the reimbursement changes being adopted under the statutory requirement that TRICARE reimburse like Medicare; that is, the 20 percent DRG increase for COVID–19 patients, the adoption of NTAPs and HVBP, and the waiver of LTCH site neutral payment reductions. A breakdown of costs, by provision, is provided in the below table. A discussion of assumptions follows.

<table>
<thead>
<tr>
<th>Provision</th>
<th>Nine-month scenario</th>
<th>Eighteen-month scenario</th>
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</thead>
<tbody>
<tr>
<td>Paragraph 199.4(b)(3)(xiv) SNF Three-Day Prior Stay Waiver</td>
<td>$0.3M</td>
<td>$0.6M</td>
</tr>
<tr>
<td>Paragraph 199.4(g)(15)(A) INDs for COVID–19</td>
<td>0.7M–2.2M</td>
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<tr>
<td>Paragraph 199.6(b)(4)) Temporary Hospitals and Freestanding ASCs Registering as Hospitals</td>
<td>0M</td>
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<tr>
<td>Paragraph 199.14(a)(1)(iii)(E)(5) NTAPs</td>
<td>27.7M–42M</td>
<td>37.1M–51.4M</td>
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<td>Paragraph 199.14(a)(1)(iii)(E)(6) HVBP</td>
<td>5.7M</td>
<td>11.6M</td>
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<td>Paragraph 199.14(a)(9) LTCH Site Neutral Payments</td>
<td>2.5M</td>
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<tr>
<td>Administrative Costs</td>
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<tr>
<td>Estimated Total Cost Impact</td>
<td>43.6M–59.4M</td>
<td>66.3M–82.1M</td>
</tr>
</tbody>
</table>

Benefits to the TRICARE Program

Depending on the impact of certain provisions of this IFR, some cost savings could be achieved from a reduction in hospitalization rates (i.e., use of treatment INDs), estimated from no savings to $40M over 18 months. The amount of cost-savings achieved will be determined by the therapies developed, how widespread their usage is, the extent to which the therapies are authorized as treatment INDs, the effectiveness of the therapies in reducing hospitalizations and/or the use of mechanical ventilators, and how long the therapies remain as INDs before transitioning to United States Food and Drug Administration-approval, clearance, or emergency use authorization.

Any benefits achieved in reduced hospitalizations and/or mechanical ventilator use are also benefits to TRICARE beneficiaries, for whom avoidance of more serious COVID–19 illness is of paramount concern. While we cannot estimate the value of this avoidance in quantitative figures, the potential long-term consequences of a serious COVID–19 illness, including permanent cardiac or lung damage, are not insignificant. If beneficiaries are able to access emerging therapies that prevent long-term consequences (including death), this will be a benefit to the beneficiary.

The largest creators of costs under this IFR (reimbursement changes) are not anticipated or intended to create any cost savings. However, these changes will benefit TRICARE institutional providers and take stress off the entire health care system by ensuring adequate reimbursement during the PHE, at a time during which hospitals are losing revenue due to reduced elective procedures and patients who delay care due to fears of contracting COVID–19 during health care encounters. Ensuring a robust health care system is of benefit to our beneficiaries and the general public, particularly in rural or underserved areas, even though this benefit is not quantifiable.

None. This rule will promote the efficient functioning of the economy and markets by modifying the regulations to better reimburse health care providers for care provided during the COVID–19 pandemic, particularly as strain on the health care economy is being felt due to reductions in higher cost elective procedures.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>Interim Final Rule Effective.</td>
<td>09/03/20</td>
<td>85 FR 54915</td>
</tr>
<tr>
<td>Interim Final Rule Comment Period End.</td>
<td>11/02/20</td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>02/00/22</td>
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</tbody>
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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: None.

Agency Contact: Erica Ferron, Defense Health Agency, Medical Benefits and Reimbursement Division, Department of Defense, Office of Assistant Secretary for Health Affairs, 16401 E Centretech
DOD—DOOOASHA

29. TRICARE Coverage of National Institute of Allergy and Infectious Disease Coronavirus Disease 2019 Clinical Trials

Priority: Other Significant.
Legal Authority: 5 U.S.C. 301; 10 U.S.C. ch 55
CFR Citation: 32 CFR 199.
Legal Deadline: None.

Abstract: The Department of Defense is finalizing an interim final rule that temporarily amended 32 CFR 199 to revise certain elements of the TRICARE program, to add coverage for National Institute of Allergy and Infectious Disease-sponsored clinical trials for the treatment or prevention of coronavirus disease 2019 (COVID–19).

Statement of Need: Pursuant to the President’s national emergency declaration and as a result of the worldwide COVID–19 pandemic, the Assistant Secretary of Defense for Health Affairs hereby temporarily modifies the regulation at 32 CFR 199.4(e)(26) to permit TRICARE coverage for National Institute of Allergy and Infectious Disease-sponsored COVID–19 phase I, II, III, and IV clinical trials for the treatment or prevention of coronavirus disease 2019 (COVID–19). This provision supports increased access to emerging therapies for TRICARE beneficiaries.

Summary of Legal Basis: This rule is issued under 10 U.S.C. 1079 giving authority and responsibility to the Secretary of Defense to administer the TRICARE program.

Alternatives:
(1) No action.
(2) The second alternative the DoD considered was implementing a more limited benefit change for COVID–19 patients by not covering phase I clinical trials. Although this would have the benefit of reimbursing only care that has more established evidence in its favor, this alternative is not preferred because early access to treatments is critical for TRICARE beneficiaries given the rapid progression of the disease and the lack of available approved treatments.

Anticipated Cost and Benefits:
Costs: We estimate the total cost for TRICARE participation in NIAID-sponsored COVID–19 clinical trials will be $3.2M for the duration of the national emergency, with an additional $4.0M for continued care for beneficiaries enrolled in clinical trials prior to termination of the national emergency. There were several assumptions we made in developing this estimate. The duration of the COVID–19 national emergency is uncertain; however, for the purposes of this estimate, we assumed the national emergency would expire on September 30, 2021. As of the drafting of this IFR, there were 27 NIAID-sponsored COVID–19 clinical trials begun since the start of the national emergency. We assumed 6.2 new trials every 30 days, for a total of 126 trials by September 2021. We assumed, based on average trial enrollment and that TRICARE beneficiaries would participate in trials at the same rate as the general population, that 4,549 TRICARE beneficiaries would participate through September 2021. Each of the assumptions in this estimate is highly uncertain, and our estimate could be higher or lower depending on real world events (more or fewer trials, a longer or shorter national emergency, and/or higher or lower participation in clinical trials by TRICARE beneficiaries).

Benefits: These changes expand the therapies available to TRICARE beneficiaries in settings that ensure informed consent of the beneficiary, and where the benefits of treatment outweigh the potential risks. Participation in clinical trials may provide beneficiaries with benefits such as reduced hospitalizations and/or use of a mechanical ventilator. Although we cannot estimate the value of avoiding these outcomes, the potential long-term consequences of serious COVID–19 illness, including permanent cardiac or lung damage, are not insignificant. Beneficiary access to emerging therapies that reduce these long-term consequences or even death can be considered to be high-value for those able to participate.

TRICARE providers will be positively affected by being able to provide their patients with a broader range of treatment options. The general public will benefit from an increased pool of available participants for the development of treatments and vaccines for COVID–19, as well as the evidence (favorable or otherwise) that results from this participation.

Risks: None. This rule will not directly affect the efficient functioning of the economy or private markets. However, increasing the pool of available participants for clinical trials may help speed the development of treatments or vaccines for COVID–19. Once effective treatments or vaccines for COVID–19 exist, individuals are likely to be more confident interacting in the public sphere, resulting in a positive impact on the economy and private markets.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>Interim Final Rule</td>
<td>10/30/20</td>
<td>85 FR 68753</td>
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<td>Comment Period End</td>
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<tr>
<td>Final Action</td>
<td>06/00/22</td>
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</tbody>
</table>

DOD—DOOOASHA

30. Expanding TRICARE Access to Care in Response to the COVID–19 Pandemic

Priority: Other Significant.
Legal Authority: 5 U.S.C. 301; 10 U.S.C. ch 55
CFR Citation: 32 CFR 199
Legal Deadline: None.

Abstract: This interim final rule with comment will temporarily amend the TRICARE regulation at 32 CFR part 199 by: (1) Adding freestanding End Stage Renal Disease facilities as a category of TRICARE-authorized institutional provider and modifying the reimbursement for such facilities; (2) adding coronavirus 2019 (COVID–19) Immunizers who are not otherwise an eligible TRICARE-authorized provider as providers eligible for reimbursement for COVID–19 vaccines and vaccine administration; (3) and adopting Medicare New COVID–19 Treatments Add-on Payments (NTCAPs).

Statement of Need: Pursuant to the President’s emergency declaration and as a result of the COVID–19 pandemic, the Assistant Secretary of Defense for Health Affairs is temporarily modifying the following regulations (except for the modifications to paragraphs 199.6(b)(4)(xxii) and 199.14(a)(1)(iii)(E)(7), which will not expire), but, in each case, only to the extent necessary to ensure that TRICARE beneficiaries have access to the most up-to-date care required for the prevention, diagnosis, and treatment of...
COVID–19, and that TRICARE continues to reimburse like Medicare, to the extent practicable, as required by statute.

The modifications to paragraphs 199.6(b)(4)(xii) and 199.14(a)(iii)(E) establish freestanding End Stage Renal Disease (ESRD) facilities as a category of TRICARE-authorized institutional provider and modify TRICARE reimbursement of freestanding ESRD facilities. These provisions will improve TRICARE beneficiary access to medically necessary dialysis and other ESRD services and supplies. These provisions also support the requirement that TRICARE reimburse like Medicare, and will help to alleviate regional health care shortages due to the COVID–19 pandemic by ensuring access to dialysis care in freestanding ESRD facilities rather than hospital outpatient departments.

The modification to paragraph 199.14(a)(iii)(E) adopts Medicare’s New COVID–19 Treatments Add-on Payment (NCTAP) for COVID–19 cases that meet Medicare’s criteria. This provision increases access to emerging COVID–19 treatments and supports the requirement that TRICARE reimburse like Medicare.

The modification to paragraph 199.6(d)(7) adds providers who administer COVID–19 vaccinations, but are not otherwise authorized under 199.6, as TRICARE-authorized providers. This provision increases access to COVID–19 vaccinations. This provision increases access to COVID–19 vaccines for eligible TRICARE beneficiaries and supports the United States (U.S.) public health goal of ending the COVID–19 pandemic.

Summary of Legal Basis: This rule is issued under 10 U.S.C. 1073(a)(2) giving authority and responsibility to the Secretary of Defense to administer the TRICARE program.

Alternatives:
(1) No action.
(2) The second alternative the Department of Defense considered was to adopt Medicare’s ESRD reimbursement methodology, the ESRD Prospective Payment System (PPS), in total. While this would have been completely consistent with the statutory provision to pay institutional providers using the same reimbursement methodology as Medicare, this alternative is not preferred because there is still a relatively low volume of TRICARE beneficiaries who receive dialysis services from freestanding ESRDs and who are not enrolled to Medicare. The cost of implementing the full ESRD PPS system is estimated to be at least $600,000.00 in start-up costs, plus ongoing administrative costs, to ensure all adjustments were made for each claim, plus additional special pricing software or algorithms. In contrast, we estimate that the option provided in this IFR can be implemented relatively quickly (within six months of publication), and for approximately $300,000.00 in start-up costs with lower ongoing administrative costs. Further, the flat rate will provide the ESRD facilities with predictability with regard to TRICARE payments and will reduce uncertainty and specialized coding or case-mix documentation requirements that may be required by the ESRD PPS, reducing the administrative burden on the provider.

To summarize, adopting the ESRD PPS was considered, but was deemed impracticable and overly burdensome to both the Government and providers due to the relative low volume of claims that will be priced and paid by TRICARE as primary under this system.

Anticipated Cost and Benefits: Health Care and Administrative Costs.

The Independent Cost A by Kennell and Associates, Inc., estimates a total of $6.8M. Only the ESRD provisions are expected to result in recurring incremental health care costs; the remaining two provisions are expected to result in one-time cost increases. For these temporary changes to the regulation, our cost estimate assumes that the majority of adults in the U.S. will be vaccinated by September 2021, based on the most recent information provided by Federal and state agencies, and, as a result, that the President’s emergency declaration and the public health emergency relating to the COVID–19 pandemic will end by September 2021. While this estimate would have the President’s emergency declaration end shortly after publication of the rule, the COVID–19 pandemic contains substantial uncertainty including the possibility of a virus variant resistant to current vaccines. As such, we find it appropriate to make these regulatory changes despite the potential short effective period, as the end of the pandemic is by no means a certainty.

Based on these factors, as well as the assumptions for each provision detailed below, we estimate that the total cost estimate for this Interim Final Rule (IFR) will be approximately $6.8M. This estimate includes approximately $0.9M in administrative costs and $5.9M in direct health care costs. $1.8M of the total cost impact is expected to be a one-time start-up cost for both the temporary and permanent provisions, while the permanent ESRD provisions are expected to result in $5M in incremental annual costs.

A breakdown of costs, by provision, is provided in the below table.

<table>
<thead>
<tr>
<th>Provision</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Freestanding ESRD Facilities as TRICARE-Authorized Institutional Providers and Modify ESRD Reimbursement</td>
<td>$5.3M</td>
</tr>
<tr>
<td>Temporarily Authorize Immunizers Providing COVID–19 Vaccines</td>
<td>0.4M</td>
</tr>
<tr>
<td>Temporarily Adopt DRG Add-On Payment for NCTAPs</td>
<td>1.1M</td>
</tr>
<tr>
<td>Estimated Total Cost Impact</td>
<td>6.8M</td>
</tr>
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Risks: None. This rule will promote the efficient functioning of the economy and markets by modifying the regulations to better reimburse health care providers for care provided during the COVID–19 pandemic, particularly as strain on the health care economy is being felt due to reductions in higher cost elective procedures. Additionally, this rule will increase the access of TRICARE beneficiaries to more

Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Agency Contact: Jahanbakhsh Badshah, Healthcare Program Specialist—Reimbursement, Department of Defense, Office of Assistant Secretary for Health Affairs, 16401 E. Contreltech Parkway, Aurora, CO 80011. Phone: 303 676–3881. Email: jahanbakhsh.badshah.civ@mail.mil.
DEPARTMENT OF EDUCATION

Statement of Regulatory Priorities

I. Introduction

The U.S. Department of Education (Department) supports States, local communities, institutions of higher education, and families in improving education and other services nationwide to ensure that all Americans, including those with disabilities and who have been underserved, receive a high-quality and safe education and are prepared for employment that provides a livable wage. We provide leadership and financial assistance pertaining to education and related services at all levels to a wide range of stakeholders and individuals, including State educational and other agencies, local school districts, providers of early learning programs, elementary and secondary schools, institutions of higher education, career and technical schools, nonprofit organizations, students, members of the public, families, and many others. These efforts are helping to advance equity, recover from the COVID–19 pandemic, and ensure that all children and students from pre-kindergarten through grade 12 will be ready for, and succeed in, postsecondary education, and employment, and that students attending postsecondary institutions, or participating in other postsecondary education options, are prepared for a profession or career.

We also vigorously monitor and enforce the implementation of Federal civil rights laws in educational programs and activities that receive Federal financial assistance from the Department, and support innovative and promising programs, research and evaluation activities, technical assistance, and the dissemination of data, research, and evaluation findings to improve the quality of education.

Overall, the laws, regulations, and programs that the Department administers will affect nearly every American during his or her life. Indeed, in the 2020–21 school year, about 56 million students attended an estimated 131,000 elementary and secondary schools in approximately 13,600 districts, and about 20 million students were enrolled in postsecondary schools. Many of these students may benefit from some degree of financial assistance or support from the Department. In developing and implementing regulations, guidance, technical assistance, evaluations, data gathering and reporting, and monitoring related to our programs, we are committed to working closely with affected persons and groups. Our core mission includes serving the most vulnerable, and facilitating equal access for all, to ensure all students receive a high-quality and safe education, and complete it with a well-considered and attainable path to a sustainable career. Toward these ends, we work with a broad range of interested parties and the general public, including families, students, and educators; State, local, and Tribal governments; other Federal agencies; and neighborhood groups, community-based early learning programs, elementary and secondary schools, postsecondary institutions, rehabilitation service providers, adult education providers, professional associations, civil rights, nonprofits, advocacy organizations, businesses, and labor organizations.

If we determine that it is necessary to develop regulations, we seek public participation at the key stages in the rulemaking process. We invite the public to submit comments on all proposed regulations through the internet or by regular mail. We also continue to seek greater public participation in our rulemaking activities through the use of transparent and interactive rulemaking procedures and new technologies.

To facilitate the public’s involvement, we participate in the Federal Docket Management System (FDMS), an electronic single Government-wide access point (www.regulations.gov) that enables the public to submit comments on different types of Federal regulatory documents and read and respond to comments submitted by other members of the public during the public comment period. This system provides the public with the opportunity to submit comments electronically on any notice of proposed rulemaking or interim final regulations open for comment as well as read and print any supporting regulatory documents.

II. Regulatory Priorities

The following are the key rulemaking actions the Department is planning for the coming year. These rulemaking actions advance the Department’s mission of “promot[ing] student achievement and preparation for global competitiveness by fostering educational excellence and ensuring equal access.” These rulemaking actions also advance the President’s priorities of ensuring that the underserved community has access to a high-quality education, regardless of background, and that government should affirmatively work to expand educational opportunities for underserved communities. During his first year in office, the President has repeatedly made clear the importance of advancing equity and opportunity for those who have historically been underserved, both as a general matter and with regard to the education system in particular. See Executive Order 13985 (On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government); Executive Order 14021 (Guaranteeing an Educational Environment Free From Discrimination on the Basis of Sex, Including Sexual Orientation or Gender Identity); Executive Order 14041 (White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity Through Historically Black Colleges and Universities); Executive Order 14045 (White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics); Executive Order 14049 (White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity for Native Americans and Strengthening Tribal Colleges and Universities); and Executive Order 14050 (White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity for Black Americans). The rulemaking actions on the Department’s agenda seek to advance the President’s priorities, as set out in these executive orders and more broadly. The rules below cover a wide range of topics, and a wide range of educational institutions—from those serving our youngest children to colleges, universities, and adult education programs. In each of these contexts, promoting equity and opportunity for students who have been historically underserved is central to the Department’s regulatory plan.

These key rulemakings include Public Service Loan Forgiveness, Income Contingent Repayment, Improving Student Loan Cancellation Authorities, Pell Grants for Prison Education Programs, State-Defined Processes for Ability to Benefit, and Civil Rights, such as Title IX Nondiscrimination on the Basis of Sex in Education Program or Activities Receiving Federal Financial Assistance. For example, the Pell Grants for Prison Education Programs rule would support increased educational opportunities for individuals who are incarcerated and provide quality options for individuals in this underserved community. Additionally, the Income Contingent Repayment rule would make student loan payments...
more affordable for borrowers, with a particular goal of helping increase educational opportunities for many low-income borrowers. The Department has also dispersed billions of dollars in funding during the COVID–19 pandemic to address inequities exacerbated by the pandemic, which targets resources to historically underserved groups of students and those students most impacted by the pandemic through the American Rescue Plan and other relief efforts.

For rulemakings that we are just beginning now, we have limited information about their potential costs and benefits. We note that some policies that were previously included in the Spring Unified Agenda, such as policies impacting the magnet schools and charter school programs, are still part of the Department’s plans but do not require regulation and, therefore, are not included as items in the Fall regulatory agenda or in this regulatory plan. We have also identified the Innovative Assessment Demonstration Authority (IADA) rulemaking as a long-term action because we are waiting for the forthcoming progress report on the initial demonstration authority to inform any potential regulatory proposal.

**Postsecondary Education/Federal Student Aid**

The Department’s upcoming higher education regulatory efforts include the following areas:

- Public Service Loan Forgiveness
- Borrower Defense to Repayment
- Improving Student Loan Cancellation Authorities
- Income Contingent Repayment
- Pell Grants for Prison Education Programs
- Gainful Employment
- 90/10 rule

These areas are focused on several general areas which include improving the rules governing student loan repayment and targeted student loan cancellation authorities and protecting students and taxpayers from poor-performing programs, among other topics. These rulemakings reflect the Department’s commitment to serving students and borrowers well and protecting them from harmful programs and practices that may derail their postsecondary and career goals. Through these regulatory efforts, the Department plans to address gaps in postsecondary outcomes, particularly those related to student loan repayment, affordability, and default. The Department is also focused on the disparate impacts by income, race/ethnicity, gender, disability status, and other demographic characteristics that may affect students’ postsecondary and career goals. For its higher education rulemakings, generally the Department uses a negotiated rulemaking process. We have selected participants for the negotiated rulemaking committees from nominees of the organizations and groups that represent the interests significantly affected by the proposed regulations. To the extent possible, we selected nominees who reflect the diversity among program participants. Specifically, the Department is currently conducting negotiated rulemaking addressing, among other things, student loan repayment and targeted student loan discharges by improving Public Service Loan Forgiveness, Borrower Defense to Repayment, and other targeted student loan cancellation authorities. On Income Contingent Repayment, the Department plans to create or adjust an income-contingent repayment plan that would allow borrowers to more easily afford their student loan payments. For Public Service Loan Forgiveness, the Department plans to streamline the process for receiving loan forgiveness after 10 years of qualifying payments on qualifying loans while engaging in public service. For Borrower Defense, the Secretary plans to amend the regulations that specify the acts or omissions of an institution of higher education that a borrower may assert as a defense to repayment of a loan made under the Federal Direct Loan Program. In Improving Student Loan Cancellation Authorities, the Department plans to propose improvements in areas where Congress has provided borrowers with relief or benefits related to Federal student loans. This includes authorities granted under the Higher Education Act (HEA) that allow the Department to cancel loans for borrowers who meet certain criteria, such as having a total and permanent disability, attending a school that closed, or having been falsely certified for a student loan. For these borrowers, the Secretary plans to amend the rules relating to borrower eligibility and streamline application requirements and the application and certification processes. To increase access to educational opportunities, the Department also plans to propose regulations that would guide correctional facilities and eligible institutions of higher education that seek to establish eligibility for the Pell Grant program for individuals who are incarcerated.

The Department also plans to conduct negotiated rulemaking on Gainful Employment and how to determine the amount of Federal educational assistance received by institutions of higher education through implementation of the 90/10 rule. For Gainful Employment, the Department plans to propose regulations on program eligibility under the HEA, including regulations that determine whether postsecondary educational programs prepare students for gainful employment in recognized occupations, and the conditions under which programs remain eligible for student financial assistance programs under title IV of the HEA. On the 90/10 rule, in response to changes to the HEA made by the American Rescue Plan Act of 2021, the Department plans to amend provisions governing whether proprietary institutions meet requirements that institutions receive at least 10 percent of their revenue from sources other than Federal education assistance funds.

**Civil Rights/Title IX**

The Secretary is planning a new rulemaking to amend its regulations implementing Title IX of the Education Amendments of 1972, as amended, consistent with the priorities of the Biden-Harris Administration. These priorities include those set forth in Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation and Executive Order 14021 on Guaranteeing an Educational Environment Free from Discrimination on the Basis of Sex, Including Sexual Orientation and Gender Identity.

**Student Privacy**

The Department is considering policy options to amend the Family Educational Rights and Privacy Act (FERPA) regulations, to update, clarify, and improve the current regulations. The proposed regulations are also needed to implement statutory amendments to FERPA contained in the Uninterrupted Scholars Act of 2013 and the Healthy, Hunger-Free Kids Act of 2010, to reflect a change in the name of the office designated to administer FERPA, and to make changes related to the enforcement responsibilities of the office concerning FERPA.

**COVID–19 Regulations**

As part of the Biden-Harris Administration’s efforts to combat COVID–19, safely reopen and support schools, and implement the American Rescue Plan Act (ARP), the Department has issued: Interim final requirements to assist states and school districts in planning for the safe return of students to school through the Office of Special Education Programs, which targets resources to historically underserved groups of students and those students most impacted by the pandemic through the American Rescue Plan and other relief efforts. The Department is also focused on the disparate impacts by income, race/ethnicity, gender, disability status, and other demographic characteristics that may affect students’ postsecondary and career goals. For its higher education rulemakings, generally the Department uses a negotiated rulemaking process. We have selected participants for the negotiated rulemaking committees from nominees of the organizations and groups that represent the interests significantly affected by the proposed regulations. To the extent possible, we selected nominees who reflect the diversity among program participants. Specifically, the Department is currently conducting negotiated rulemaking addressing, among other things, student loan repayment and targeted student loan discharges by improving Public Service Loan Forgiveness, Borrower Defense to Repayment, and other targeted student loan cancellation authorities. On Income Contingent Repayment, the Department plans to create or adjust an income-contingent repayment plan that would allow borrowers to more easily afford their student loan payments. For Public Service Loan Forgiveness, the Department plans to streamline the process for receiving loan forgiveness after 10 years of qualifying payments on qualifying loans while engaging in public service. For Borrower Defense, the Secretary plans to amend the regulations that specify the acts or omissions of an institution of higher education that a borrower may assert as a defense to repayment of a loan made under the Federal Direct Loan Program. In Improving Student Loan Cancellation Authorities, the Department plans to propose improvements in areas where Congress has provided borrowers with relief or benefits related to Federal student loans. This includes authorities granted under the Higher Education Act (HEA) that allow the Department to cancel loans for borrowers who meet certain criteria, such as having a total and permanent disability, attending a school that closed, or having been falsely certified for a student loan. For these borrowers, the Secretary plans to amend the rules relating to borrower eligibility and streamline application requirements and the application and certification processes. To increase access to educational opportunities, the Department also plans to propose regulations that would guide correctional facilities and eligible institutions of higher education that seek to establish eligibility for the Pell Grant program for individuals who are incarcerated.

The Department also plans to conduct negotiated rulemaking on Gainful Employment and how to determine the amount of Federal educational assistance received by institutions of higher education through implementation of the 90/10 rule. For Gainful Employment, the Department plans to propose regulations on program eligibility under the HEA, including regulations that determine whether postsecondary educational programs prepare students for gainful employment in recognized occupations, and the conditions under which programs remain eligible for student financial assistance programs under title IV of the HEA. On the 90/10 rule, in response to changes to the HEA made by the American Rescue Plan Act of 2021, the Department plans to amend provisions governing whether proprietary institutions meet requirements that institutions receive at least 10 percent of their revenue from sources other than Federal education assistance funds.
Funds; a request for information regarding implementation of the statutory requirements for ARP’s maintenance of equity (a first-of-its-kind requirement to protect schools and districts serving students from low-income backgrounds from harmful budget cuts); final requirements to clarify the requirements applicable to the ARP Emergency Assistance to Non-Public Schools program; amended regulations so that an institution of higher education (IHE) may appropriately determine which individuals currently or previously enrolled at an institution are eligible to receive emergency financial aid grants to students under the Higher Education Emergency Relief programs; and a final rule regarding the allocations to Historically Black Colleges and Universities (HBCUs) awarded under section 314(a)(2) of the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSAA).

III. Principles for Regulating

Over the next year, we may need to issue other regulations because of new legislation or programmatic changes. In doing so, we will follow the Principles for Regulating, which determine when and how we will regulate. Through consistent application of those principles, we have eliminated unnecessary regulations and identified situations in which major programs could be implemented without regulations or with limited regulatory action.

In deciding when to regulate, we consider the following:

- Whether regulations are essential to promote quality and equality of opportunity in education.
- Whether a demonstrated problem cannot be resolved without regulation.
- Whether regulations are necessary to provide a legally binding interpretation to resolve ambiguity.
- Whether entities or situations subject to regulation are similar enough that a uniform approach through regulation would be meaningful and do more good than harm.
- Whether regulations are needed to protect the Federal interest, that is, to ensure that Federal funds are used for their intended purpose and to eliminate fraud, waste, and abuse.

In deciding how to regulate, we are mindful of the following principles:

- Regulate no more than necessary.
- Minimize burden to the extent possible and promote multiple approaches to meeting statutory requirements if possible.
- Encourage coordination of federally funded activities with State and local reform activities.
- Ensure that the benefits justify the costs of regulating.
- To the extent possible, establish performance objectives rather than specify the behavior or manner of compliance a regulated entity must adopt.
- Encourage flexibility, to the extent possible and as needed to enable institutional forces to achieve desired results.

ED—OFFICE FOR CIVIL RIGHTS (OCR)

Proposed Rule Stage

31. Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance


Unfunded Mandates: Undetermined.

Legal Authority: 20 U.S.C. 1681 et seq.

Legal Deadline: None.

Abstract: The Department plans to propose to amend its regulations implementing Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 et seq., consistent with the priorities of the Biden-Harris Administration. These priorities include those set forth in Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation and Executive Order 14021 on Guaranteeing an Educational Environment Free from Discrimination on the Basis of Sex, Including Sexual Orientation and Gender Identity. We anticipate this rulemaking may include, but would not be limited to, amendments to 34 CFR 106.8 (Designation of coordinator, dissemination of policy, and adoption of grievance procedures), 106.30 (Definitions), 106.44 (Recipient’s response to sexual harassment), and 106.45 (Grievance process for formal complaints of sexual harassment).

Statement of Need: This rulemaking is necessary to align the Title IX regulations with the priorities of the Biden-Harris Administration, including those set forth in the Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (E.O. 13988) and the Executive Order on Guaranteeing an Educational Environment Free from Discrimination on the Basis of Sex, Including Sexual Orientation and Gender Identity (E.O. 14021).

Summary of Legal Basis: We are conducting this rulemaking under 20 U.S.C. 1681 et seq.

ED—OFFICE OF PLANNING, EVALUATION AND POLICY DEVELOPMENT (OPEPD)

Proposed Rule Stage

32. Family Educational Rights and Privacy Act

Priority: Other Significant.


Legal Deadline: None.

Abstract: The Department plans to propose to amend the Family Educational Rights and Privacy Act (FERPA) regulations, 34 CFR part 99, to update, clarify, and improve the current regulations by addressing outstanding policy issues, such as clarifying the definition of “education records” and clarifying provisions regarding disclosures to comply with a judicial order or subpoena. The proposed regulations are also needed to implement statutory amendments to FERPA contained in the Uninterrupted Scholars Act of 2013 and the Healthy, Hunger-Free Kids Act of 2010, to reflect a change in the name of the office designated to administer FERPA, and to make changes related to the enforcement responsibilities of the office concerning FERPA.

Statement of Need: These regulations are needed to implement amendments to FERPA contained in the Healthy,
Hunger-Free Kids Act of 2010 (Pub. L. 111206) and the Uninterrupted Scholars Act (USA) of 2013 (Pub. L. 112278); to provide needed clarity regarding the definitions of terms and other key provisions of FERPA; and to make necessary changes identified as a result of the Department’s experience administering FERPA and the current regulations. A number of the proposed changes reflect the Department’s existing guidance and interpretations of FERPA.


Alternatives: These are discussed in the preamble to the proposed regulations.

Anticipated Cost and Benefits: These are discussed in the preamble to the proposed regulations.

Risks: These are discussed in the preamble to the proposed regulations.

Required: proposed regulations.

The preamble to the proposed regulations.

Statement of Need: This rulemaking is necessary to reflect changes to the HEA made by the American Rescue Plan Act, governing whether proprietary institutions meet the requirement in 34 CFR 668.14(b)(16) that these institutions receive at least 10 percent of their revenue from sources other than Federal education assistance funds.

Summary of Legal Basis: We are conducting this rulemaking under the following authorities: 20 U.S.C. 1085, 1088, 1091, 1092, 1094, 1099a–3, and 1099c.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

Summary of Legal Basis: We are conducting this rulemaking under the following authorities: 20 U.S.C. 1082(a)(5), (a)(6); 20 U.S.C. 1087(a); 20 U.S.C. 1087(h); 20 U.S.C. 1221e–3; 20 U.S.C. 1226a–1; 20 U.S.C. 1234(a); and 31 U.S.C. 3711.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

ED—OFFICE OF POSTSECONDARY EDUCATION (OPE)

Prerule Stage

33. Determining the Amount of Federal Education Assistance Funds Received by Institutions of Higher Education (90/10)

Priority: Economically Significant.

Major under 5 U.S.C. 801.

Unfunded Mandates: Undetermined.


CFR Citation: 34 CFR 668.28.

Legal Deadline: None.

Abstract: To reflect changes to the HEA made by the American Rescue Plan Act, the Secretary plans to propose to amend the Student Assistance General Provisions (34 CFR 668.28 Non-Title IV revenue) governing whether proprietary institutions meet the requirement in 34 CFR 668.14(b)(16) that institutions receive at least 10 percent of their revenue from sources other than Federal education assistance funds.

Statement of Need: This rulemaking is necessary to reflect changes to the HEA made by the American Rescue Plan Act, governing whether proprietary institutions meet the requirement in 34 CFR 668.14(b)(16) that these institutions receive at least 10 percent of their revenue from sources other than Federal education assistance funds.

Summary of Legal Basis: We are conducting this rulemaking under the following authorities: 20 U.S.C. 1085, 1088, 1091, 1092, 1094, 1099a–3, and 1099c.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

ED—OPE

Proposed Rule Stage

34. Borrower Defense

Priority: Economically Significant.

Major under 5 U.S.C. 801.

Unfunded Mandates: Undetermined.


CFR Citation: 34 CFR 30; 34 CFR 668; 34 CFR 674; 34 CFR 682; 34 CFR 683; 34 CFR 686.

Legal Deadline: None.

Abstract: The Secretary proposes to amend regulations that determine what acts or omissions of an institution of higher education a borrower may assert as a defense to repayment of a loan made under the Federal Direct Loan and Federal Family Education Loan Programs and specify the consequences of such borrower defenses for borrowers, institutions, and the Secretary.

Statement of Need: This rulemaking is necessary to determine what acts or omissions of an institution of higher education a borrower may assert as a defense to repayment of a loan made under the Federal Direct Loan Program and specify the consequences of such borrower defenses for borrowers, institutions, and the Secretary.

Summary of Legal Basis: We are conducting this rulemaking under the following authorities: 20 U.S.C. 1082(a)(5), (a)(6); 20 U.S.C. 1087(a); 20 U.S.C. 1087(h); 20 U.S.C. 1221e–3; 20 U.S.C. 1226a–1; 20 U.S.C. 1234(a); and 31 U.S.C. 3711.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.
ED—OPE
35. Pell Grants for Prison Education Programs

Priority: Economically Significant.
Major status under 5 U.S.C. 801 is undetermined.

Unfunded Mandates: Undetermined.
Legal Authority: 20 U.S.C. 1001–1002; 20 U.S.C. 1070a, 1070a–1, 1070b, 1070c–1, 1070c–2, 1070g; 20 U.S.C. 1085, 1087aa–1087hh, 1088, 1091; 1094; 1099b, and 1099c; 42 U.S.C. 2753
CFR Citation: 34 CFR 600.20; 34 CFR 668.8.
Legal Deadline: None.
Abstract: The Consolidated Appropriation Act, 2021 defines prison education programs for purposes of Pell Grant eligibility. The Department plans to propose regulations that would guide correctional facilities and eligible institutions of higher education that seek to establish eligibility for the Pell Grant program.

Statement of Need: These regulations are necessary to increase access to educational opportunities for individuals who are incarcerated because research demonstrates that high-quality prison education programs increase the knowledge and skills necessary to obtain high-quality and stable employment.

Summary of Legal Basis: These regulations are being issued under the following authorities: 20 U.S.C. 1001–1002; 20 U.S.C. 1070a, 1070a–1, 1070b, 1070c–1, 1070c–2, 1070g; 20 U.S.C. 1085, 1087aa–1087hh, 1088, 1091; 1094; 1099b, and 1099c; 42 U.S.C. 2753.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: Undetermined.

Federalism: Undetermined.
Agency Contact: Aaron Washington, Department of Education, Office of Postsecondary Education, 400 Maryland Avenue SW, Room 294–12, Washington, DC 20202. Phone: 202 453–7241, Email: aaron.washington@ed.gov. RIN: 1840–AD54

ED—OPE
36. Gainful Employment

Priority: Economically Significant.
Major under 5 U.S.C. 801.

Unfunded Mandates: Undetermined.
CFR Citation: 34 CFR 668; 34 CFR 600.
Legal Deadline: None.
Abstract: The Secretary plans to propose to amend 34 CFR parts 668 and 600 on institution and program eligibility under the HEA, including regulations that determine whether postsecondary educational programs prepare students for gainful employment in recognized occupations, and the conditions under which institutions and programs remain eligible for student financial assistance programs under Title IV of the HEA.

Statement of Need: This rulemaking is necessary to determine whether postsecondary educational programs prepare students for gainful employment and the conditions under which institutions and programs remain eligible for student financial assistance programs under Title IV of the HEA.


Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

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Regulatory Flexibility Analysis
Required: Undetermined.
Small Entities Affected: Businesses.

Federalism: Undetermined.
Agency Contact: Gregory Martin, Department of Education, Office of Postsecondary Education, 400 Maryland Avenue SW, Room 2C136, Washington, DC 20202. Phone: 202 453–7535, Email: gregory.martin@ed.gov. RIN: 1840–AD57

ED—OPE
37. Improving Student Loan Cancellation Authorities

Priority: Economically Significant.
Major under 5 U.S.C. 801.

Unfunded Mandates: Undetermined.
CFR Citation: 34 CFR 674; 34 CFR 682; 34 CFR 685.
Legal Deadline: None.
Abstract: The Department plans to propose improvements in areas where Congress has provided borrowers with relief or benefits related to Federal student loans. This includes authorities granted under the HEA that allow the Department to cancel loans for borrowers who meet certain criteria, such as: (a) Being totally and permanently disabled; (b) attending a school that recently closed; or (c) having been falsely certified as able to benefit from a program despite not having a high school diploma or its recognized equivalent. For these borrowers, the Secretary plans to amend regulations to improve borrower eligibility, application requirements, and processes.

Statement of Need: This rulemaking is necessary to improve areas where Congress has provided borrowers with relief or benefits related to Federal student loans, including to improve borrower eligibility, application requirements, and processes.

Summary of Legal Basis: We are conducting this rulemaking under 20 U.S.C. 1087; 20 U.S.C. 1087dd

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the potential cost and benefits and cannot estimate them at this time.

Risks: We have limited information about the risks at this time.

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ED—OPE

38. Income Contingent Repayment

Legal Authority: 20 U.S.C. 1087e
CFR Citation: 34 CFR 685.
Legal Deadline: None.
Abstract: Using the income-contingent repayment (ICR) authority under the Higher Education Act of 1965, the Secretary of Education may create or adjust income-driven repayment plans to cap borrower payments at a set share of their income. The Department will propose improvements to these plans in 34 CFR part 685.

Statement of Need: This rulemaking is necessary to make improvements to the income-driven repayment plans created under the ICR authority in Higher Education Act of 1965 that allows the Secretary to cap payments at a set share of a borrower’s income.

Summary of Legal Basis: The Department is conducting this rulemaking under 20 U.S.C. 1087e.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: Undetermined.
Federalism: Undetermined.

Agency Contact: Jennifer Hong, Director, Policy Coordination Group, Department of Education, 400 Maryland Avenue SW, Room 287–23, Washington, DC 20202, Phone: 202 453–7805, Email: jennifer.hong@ed.gov.
RIN: 1840–AD69

ED—OPE

39. Public Service Loan Forgiveness

Unfunded Mandates: Undetermined.
Legal Authority: 20 U.S.C. 1087e
CFR Citation: 34 CFR 685.
Legal Deadline: None.
Abstract: The Higher Education Act of 1965 allows borrowers to receive loan forgiveness after 10 years of qualifying payments on qualifying loans while engaging in public service. The Department will propose improvements to this program in 34 CFR part 685.

Statement of Need: This rulemaking is necessary to make improvements that more closely align the Public Service Loan Forgiveness program with the statute and purpose of the program.

Summary of Legal Basis: We are conducting this rulemaking under 20 U.S.C. 1087e.

Alternatives: We have limited information about the alternatives at this time.

Anticipated Cost and Benefits: We have limited information about the anticipated costs and benefits at this time.

Risks: We have limited information about the risks at this time.

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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: Undetermined.
Federalism: Undetermined.

Agency Contact: Jennifer Hong, Director, Policy Coordination Group, Department of Education, 400 Maryland Avenue SW, Room 287–23, Washington, DC 20202, Phone: 202 453–7805, Email: jennifer.hong@ed.gov.
RIN: 1840–AD70

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Statement of Regulatory and Deregulatory Priorities

The Department of Energy (Department or DOE) makes vital contributions to the Nation’s welfare through its activities focused on improving national security, energy supply, energy efficiency, environmental remediation, and energy research. The Department’s mission is to:

• Promote dependable, affordable and environmentally sound production and distribution of energy;
• Advance energy efficiency and conservation;
• Provide responsible stewardship of the Nation’s nuclear weapons;
• Provide a responsible resolution to the environmental legacy of nuclear weapons production; and
• Strengthen U.S. scientific discovery, economic competitiveness, and improve quality of life through innovations in science and technology.

The Department’s regulatory activities are essential to achieving its critical mission and to implementing the President’s clean energy and climate initiatives. Among other things, the Regulatory Plan and the Unified Agenda contain the rulemakings the Department will be engaged in during the coming year to fulfill the Department’s commitment to meeting deadlines for issuance of energy conservation standards and related test procedures. The Regulatory Plan and Unified Agenda also reflect the Department’s continuing commitment to cut costs, reduce regulatory burden, and increase responsiveness to the public.

Review of Regulations Under Executive Order 13990

Pursuant to Executive Order 13990, “Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis,” DOE reviewed all regulations, orders, guidance documents and policies promulgated or adopted between January 20, 2017, and January 20, 2021, and determined whether these actions are consistent with the policy goals of protecting public health and the environment, including reducing greenhouse gas emissions and bolstering the Nation’s resilience to the impacts of climate change. DOE identified fourteen rulemakings that the Department will review under E.O. 13990.

In response to E.O. 13990, DOE published ten notices of proposed rulemakings or technical determinations re-evaluating rulemakings finalized in the prior four years. Four of these
publications were explicitly required to be published in 2021. First, DOE published two notices of proposed rulemaking in 2021 that remove unnecessary obstacles to DOE’s ability to develop energy conservation standards and test procedures for consumer products and commercial/industrial equipment. Second, DOE published two technical determinations that determined that the latest version of a commercial building code and residential building code are more efficient than the prior versions of these codes, paving the path for states to adopt these codes.

Other 2021 proposed Departmental appliance standards program actions triggered by E.O. 13990 but based on DOE statutory authorities included a rule to revert to the prior, water-saving definition of showerheads; a rule to remove a product class for dishwashers, clothes washers and clothes dryers that had the effect of removing standards from these products; a rule to streamline the test procedure waiver process; a rule to broaden the definition of general service lamps; and a rule proposing to reinterpret a features provision for some types of consumer products and commercial equipment.

**Energy Efficiency Program for Consumer Products and Commercial Equipment**

The Energy Policy and Conservation Act requires DOE to set appliance efficiency standards at levels that achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. The Department continues to follow its schedule for setting new appliance efficiency standards by both addressing its backlog of rulemakings with missed statutory deadlines and advancing rulemakings with upcoming statutory deadlines. In the August 2021 Energy Policy Act of 2005 Report to Congress, DOE notes that it plans to publish 31 actions relating to energy conservation standards, including four final rules, and 31 actions related to test procedures, including six final rules, before the end of 2021. See: [https://www.energy.gov/eere/buildings/reports-and-publications](https://www.energy.gov/eere/buildings/reports-and-publications). These rulemakings are expected to save American consumers billions of dollars in energy costs over a 30-year timeframe.

In the Department’s 2021 Fall Regulatory Plan, DOE is highlighting three important appliance rules. The first rule is “Energy Conservation Standards for Commercial Water Heating Equipment.” DOE estimates that the energy conservation standards rulemaking for commercial water heating-equipment will result in energy savings for combined natural gas and electricity of up to 1.8 quads over 30 years and the net benefit to the Nation will be between $2.26 billion and $6.75 billion.

The second rule is “Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment.” This rulemaking is focused on both the procedural requirements as well as the methodologies used to establish all DOE energy conservation standards and their related test procedures. DOE anticipates that the contemplated revisions would allow DOE to eliminate inefficiencies that lengthen the rulemaking process and consume DOE and stakeholder resources without appreciable benefit, while not affecting the ability of the public to participate in the agency’s rulemaking process. Eliminating these inefficiencies would allow DOE to more quickly develop energy conservation standards that deliver benefits to the Nation, including environmental benefits such as reductions in greenhouse gas emissions.

The third rule is “Backstop Requirement for General Service Lamps.” This rulemaking would codify in the Code of Federal Regulations the 45 lumens per watt backstop requirement for general service lamps (“GSLs”) that Congress prescribed in the Energy Policy and Conservation Act, as amended. Codifying the statutory standard, which would also prohibit sales of GSLs that do not meet a minimum 45 lumens per watt standard, is estimated to result in total net benefits of $3.3 billion to $4.9 billion per year.

**Federal Agency Leadership in Climate Change**

Beyond the appliance program, DOE is supporting Federal agency leadership in climate change in various ways, including in its Federal government energy efficiency rulemakings. DOE is highlighting one rule supporting Federal agency leadership in climate change under the Energy Conservation and Production Act. The rule establishes baseline Federal energy efficiency performance standards for the construction of new Federal commercial and multi-family high-rise residential buildings. The total incremental first cost savings under the rule is $32.67 million per year, with a potential cost reduction in new Federal construction costs of 0.85%, and life-cycle cost net savings of $161.9 million. Compared to the prior building standard, DOE expects a 4,472,870 metric ton reduction in carbon dioxide emissions over 30 years.

**DOE—ENERGY EFFICIENCY AND RENEWABLE ENERGY (EE)**

**Proposed Rule Stage**

**40. Energy Conservation Standards for Commercial Water Heating Equipment**

**Priority:** Economically Significant. Major under 5 U.S.C. 801.

**Unfunded Mandates:** This action may affect the private sector under Public Law 104–4.

**Legal Authority:** 42 U.S.C. 6313(a)(6)(C) and (vi)

**CFR Citation:** 10 CFR 429: 10 CFR 431.

**Legal Deadline:** Other, Statutory, Subject to 6-year-look-back in 42 U.S.C. 6313(a)(6)(C).

**Abstract:** Once completed, this rulemaking will fulfill the U.S. Department of Energy’s (DOE) statutory obligation under the Energy Policy and Conservation Act, as amended, (EPCA) to either propose amended energy conservation standards for commercial water heaters and hot water supply boilers, or determine that the existing standards do not need to be amended. (Unfired hot water storage tanks and commercial heat pump water heaters are being considered in a separate rulemaking.) DOE must determine whether national standards more stringent than those that are currently in place would result in a significant additional amount of energy savings and whether such amended national standards would be technologically feasible and economically justified.

**Statement of Need:** DOE is required under 42 U.S.C. 6313(a)(6)(C) to consider the need for amended performance-based energy conservation standards for commercial water heaters. This rulemaking is being conducted to satisfy that requirement by evaluating potential standards related to certain classes of commercial water heating equipment.

**Summary of Legal Basis:** This rulemaking is being conducted under DOE’s authority pursuant to 42 U.S.C. 6311, which establishes the agency’s legal authority over water heaters as one type of covered equipment that DOE may regulate, and 42 U.S.C. 6313(a)(6)(C), which requires DOE to conduct a rulemaking to consider the need for amended performance-based energy conservation standards for this equipment.

**Alternatives:** Under EPCA, DOE shall either establish an amended uniform national standard for this equipment at the minimum level specified in the
amended ASHRAE/IES Standard 90.1, unless the Secretary determines, by rule published in the Federal Register, and supported by clear and convincing evidence, that adoption of a uniform national standard more stringent than the amended ASHRAE/IES Standard 90.1 for this equipment would result in significant additional conservation of energy and is technologically feasible and economically justified (42 U.S.C. 6313(a)(6)(A)—(C)).

Anticipated Cost and Benefits: DOE preliminarily determined that the anticipated benefits to the Nation of the proposed energy conservation standards for the subject commercial water heating equipment would outweigh the burdens DOE estimates that potential amended energy conservation standards for commercial water heaters may result in energy savings for combined natural gas and electricity of 1.8 quads over 30 years and the net benefit to the Nation of between $2.26 billion and $6.75 billion.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes.  
**Small Entities Affected:** Businesses.  
**Government Levels Affected:** None.  
**URL For Public Comments:** www.regulations.gov/#docketDetail;D=EERE-2014-BT-STD-0042.

**Agency Contact:** Julia Hegarty, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, Phone: 240 597–6737, Email: julia.hegarty@ee.energy.gov.  
**Related RIN:** Related to 1904–AD39.  
**RIN:** 1904–AD34

**DOE—EE**

**41. Backstop Requirement for General Service Lamps**

**Priority:** Economically Significant. Major under 5 U.S.C. 801.  
**Legal Authority:** 42 U.S.C. 6295(i)(6)(A)

**CFR Citation:** 10 CFR 430.  
**Legal Deadline:** Other, Statutory, Subject to 7-year-lookback in 42 U.S.C. 6293(b).

**Abstract:** The U.S. Department of Energy (DOE) proposes to codify the 45 lumens per watt ("lm/W") backstop requirement for general service lamps (GSLs) that Congress prescribed in the Energy Policy and Conservation Act, as amended. DOE proposes this backstop requirement apply because DOE failed to complete a rulemaking regarding general service lamps in accordance with certain statutory criteria. This proposal represents a departure from DOE’s previous determination published in 2019 that the backstop requirement was not triggered. DOE re-evaluates its previous determination that the backstop was not triggered in accordance with the review requirement under E.O. 13990, “Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis,” 86 FR 7037 (January 25, 2021).

**Statement of Need:** Under the Energy Policy and Conservation Act (EPCA), as amended, if DOE fails to complete a rulemaking regarding general service lamps (GSL’s) in accordance with certain statutory criteria, the Secretary of Energy (Secretary) must prohibit the sale of any GSL that does not meet a minimum efficacy of 45 lumens per watt. In two final rules published on September 5, 2019 and December 27, 2019, DOE determined that this statutory backstop requirement for GSLs was not triggered. DOE now revisits this determination and proposes to determine that the statutory backstop does not apply, consistent with its statutory obligations under EPCA. This action was triggered in part by Executive order 13990, which specifically instructed DOE to examine the GSL rules.

**Anticipated Cost and Benefits:** Codifying the statutory standard, which would also prohibit sales of GSLs that do not meet a minimum 45 lumens per watt standard, is estimated to result in total net benefits of 3.3 billion to $4.9 billion per year.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Undetermined.  
**Government Levels Affected:** Undetermined.  
**Agency Contact:** Stephanie Johnson, General Engineer, Department of Energy, Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, Building Technologies Office, EET5B, Washington, DC 20585, Phone: 202 287–1943, Email: stephanie.johnson@ee.energy.gov.  
**RIN:** 1904–AF09

**DOE—EE**

**42. Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings Baseline Standards Update**

**Priority:** Other Significant.  
**Legal Authority:** 42 U.S.C. 6834  
**CFR Citation:** 10 CFR 433  

**Abstract:** The U.S. Department of Energy (DOE) is working on a final rule to implement provisions in the Energy Conservation and Production Act (ECPA) that require DOE to update the baseline Federal energy efficiency performance standards for the construction of new Federal commercial and multi-family high-rise residential buildings. This rule would update the baseline Federal commercial standard to the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1–2019, if the Secretary determines that the baseline Federal energy efficiency performance standards should be updated to reflect the new standard, based on the cost-effectiveness of the requirements under the amendment.

**Statement of Need:** This rule addresses DOE’s statutory obligation under ECPA to review the newest version of ASHRAE 90.1, that is, ASHRAE 90.1–2019, and update the energy efficiency performance standards for federal commercial and multi-family, high-rise buildings to reflect the new version of this industry standard. The rule will also support federal agency
leadership in addressing climate change by reducing energy use in Federal buildings and reducing emissions.

**Anticipated Cost and Benefits:** This rule is expected to result in 432.67 million annual incremental first-cost savings and annual life-cycle cost net savings of $161.9 million. Furthermore, compared to the prior Federal buildings standard, DOE expects a 4,472,870 metric ton reduction in carbon dioxide emissions over 30 years.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No.

**Government Levels Affected:** Federal.


**RIN:** 1904–AE44

**DOE—EE**


**Priority:** Other Significant.

**Legal Authority:** 42 U.S.C. 6191 to 6317

**CFR Citation:** 10 CFR 430, subpart C, App. A; 10 CFR 431.

**Legal Deadline:** None.

**Abstract:** The U.S. Department of Energy (“DOE” or “the Department”) is finalizing its revisions to the Department’s current rulemaking guidance titled “Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment” (“Process Rule”), which was last modified in 2020. These proposed revisions, which are the first of two sets of revisions to the Process Rule that DOE intends to propose, are consistent with longstanding DOE practice prior to the 2020 amendment and would remove unnecessary obstacles to DOE’s ability to meet its statutory obligations under the Energy Policy and Conservation Act (“EPCA”) and other applicable law. These proposed changes would include modifying the Process Rule to remove its mandatory application, removing its recently-added threshold for determining when significant energy savings is met, removing the current provision regarding the use of a comparative analysis when selecting potential energy conservation standards, and reverting to its prior guidance for determining whether a trial standard level is economically justified, among other changes. DOE is undertaking this action as required by E.O. 13990, “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis”; 86 FR 7037 (January 25, 2021).

**Statement of Need:** On February 14, 2020 and August 19, 2020, DOE published two final rules (“Process Rule Amendment Final Rules”) that made significant revisions to the existing Process Rule. DOE is reconsidering the merits of the approach taken by these 2020 revisions to the Process Rule—specifically, the one-fits-all rulemaking approach and the added rulemaking steps now required under the Process Rule. In its proposed revisions, the Department seeks to ensure that the document remains consistent with DOE’s legal obligations under the Energy Policy and Conservation Act, as amended. DOE’s action in examining the current Process Rule was triggered in part by Executive Order 13990, which specifically instructed DOE to examine the Process Rule.

**Anticipated Cost and Benefits:** DOE anticipates that the contemplated revisions would allow DOE to eliminate inefficiencies that lengthen the rulemaking process and consume DOE and stakeholder resources without appreciable benefit, while not affecting the ability of the public to participate in the agency’s rulemaking process. Eliminating these inefficiencies would allow DOE to more quickly develop energy conservation standards that deliver benefits to the Nation, including environmental benefits, such as reductions in greenhouse gas emissions, that DOE is directed to pursue under E.O. 13990. DOE notes that these revisions would not dictate any particular rulemaking outcome in an energy conservation standard or test procedure rulemaking.

**Timetable:**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Statement of Regulatory Priorities for Fiscal Year 2022**

As the federal agency with principal responsibility for protecting the health of all Americans and for providing essential human services, the Department of Health and Human Services (HHS or the Department) implements programs that strengthen the health care system; advance scientific knowledge and innovation; and improve the health, safety, and wellbeing of the American people.

The Department’s Regulatory Plan for Fiscal Year 2022 delivers on the Biden-Harris Administration’s commitment to tackle the COVID–19 pandemic, build, and expand access to affordable health care, address health disparities, increase health equity, and promote the wellbeing of children and families:

- This agenda expands access to quality, affordable health care for all Americans, with rules to provide evidence-based behavioral health treatment via telehealth and rules to streamline enrollment and improve access to care in Medicaid and the Children’s Health Insurance Program (CHIP) to ensure that children and families eligible for these programs are able to maintain coverage and obtain needed care.
- As we work to expand access to affordable health care, we will simultaneously tackle disparities that persist in who gain access to care. Forthcoming rules—including one designed to prevent discrimination in accessing care and coverage—serve to protect every person’s right to access the health care they need, no matter where they live or who they are.
I. Building and Expanding Access to Affordable Health Care

Since its enactment, the Affordable Care Act (ACA) has dramatically reduced the number of uninsured Americans while strengthening consumer protections and improving our nation’s health care system. Yet high uninsured rates and other barriers to care continue to persist, compounded by the health and economic challenges facing Americans nationwide due to the COVID–19 pandemic. From day one, the Biden-Harris Administration has been focused on closing these gaps in coverage and access. The American Rescue Plan (ARP) alongside the ACA and executive actions by the Biden-Harris Administration have already led to lower premiums for consumers and more opportunities to gain coverage, achieving record-high enrollment in ACA Marketplace and Medicaid coverage.

The Department plans to continue expanding access to affordable health care over the next year, including through its regulatory actions. Secretary Becerra’s regulatory priorities in this area include: Enhancing coverage and access for Americans in the ACA Marketplace, Medicaid, CHIP, and Medicare; expanding the accessibility and affordability of drugs and medical products; addressing behavioral health needs; and streamlining the secure exchange of health information.

Enhancing Coverage and Access in the ACA Marketplace, Medicaid, CHIP, and Medicare

The Department will take several regulatory actions in the next year building on the success of the ACA and improving access to care for Americans. In his Executive Order on Strengthening Medicaid and the Affordable Care Act (E.O. 14009), President Biden asked the Department to consider a range of actions, including actions that would protect and strengthen Medicaid. Following this regulatory review, the Department is issuing two rules. First, the Department will issue a proposed rule on Assuring Access to Medicaid and Children’s Health Insurance Program (CHIP) Services. Together, Medicaid and CHIP cover nearly one in four Americans and provide access to a broad array of health benefits and services critical to underserved populations, including low-income adults, children, pregnant women, elderly, and people with disabilities. This rule would empower the Department to assure and monitor equitable access to services in Medicaid and CHIP.

Additionally, the Department will issue a proposed rule on Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes. Although considerable progress has been made in these areas, gaps remain in states’ ability to seamlessly process beneficiaries’ eligibility and enrollment. This rule would streamline eligibility and enrollment processes for all Medicaid and CHIP populations and create new enrollment pathways to maximize enrollment and retention of eligible individuals. The first step to ensuring access to services is making certain that people can maintain a consistent source of high-quality coverage.

The Department also plans to issue a proposed rule on Requirements for Rural Emergency Hospitals. This rule would establish health and safety requirements as Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) participating in Medicare or Medicaid, in accordance with Section 125 of the Consolidated Appropriations Act, 2021, and will establish payment policies and payment rates for REHs. This rule will aim to address barriers to health care, uninsured social needs, and other health challenges and risks faced by rural communities.

Improving access to care for populations with ACA Marketplace coverage is also a regulatory priority of the Department. For instance, the Department will issue a proposed rule to protect patients’ access to care and promote competition by ensuring that plans do not engage in unlawful discrimination against health care providers. While the ACA’s provider nondiscrimination protections are currently set forth in guidance, the No Surprises Act directs the Department to implement these protections through regulation.

The Department will also work to ensure access to benefits and services afforded under the law. A critical part of this work will include amending regulations on contraceptive coverage which guarantee cost-free coverage to the consumer under the ACA. In addition to the actions described above, the Department’s regulatory agenda includes several payment rules and notices issued annually by the Centers for Medicare & Medicaid Services (CMS) that affect Medicare, Medicaid, and the ACA Marketplace. These rules, though they are not included in the HHS Regulatory Plan, will include policies in service of the Secretary’s priority of expanding access to affordable, high-quality health care.

Expanding the Accessibility and Affordability of Drugs and Medical Products

The Department is committed to improving Americans’ access to affordable drugs and medical products. Earlier this year, the Department issued a proposed rule entitled Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations. Consistent with President Biden’s Executive Order on Promoting Competition in the American Economy (E.O. 14036), this rule proposes to establish a new category of over-the-counter hearing aids. If finalized, the rule would allow hearing aids within this category to be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist. This action will address existing barriers on access to hearing aids, improve consumer choice, and have a direct impact on quality of life.

Over the next year, the Department will continue pursuing greater accessibility and affordability for Americans in need of drugs and medical products, consistent with the Department’s Comprehensive Plan for Addressing High Drug Prices, released in September 2021. For example, the Department plans to issue a proposed...
First, the Department will issue a proposed rule on Treatment of Opioid Use Disorder With Extended Take Home Doses of Methadone. This rule would propose revisions to Substance Abuse and Mental Health Services Administration (SAMHSA) regulations to make permanent regulatory flexibilities for opioid treatment programs to provide extended take-home doses of methadone to patients when it is safe and appropriate to do so. Likewise, the Department also plans to issue a proposed rule on Treatment of Opioid Use Disorder with Buprenorphine Utilizing Telehealth. This rule would propose revisions to SAMHSA regulations to permanently allow opioid treatment programs and certain other providers to provide buprenorphine via telehealth. Both changes would allow more patients to receive comprehensive opioid use disorder treatment and could address barriers to treatment such as transportation, geographic proximity, employment, or other required activities of daily living.

Furthermore, the Department, working closely with the Department of Labor, will issue a proposed rule on the Mental Health Parity and Addiction Equity Act (MHPAEA) and the Consolidated Appropriations Act, 2021. The MHPAEA is a federal law that prevents group health plans and health insurance issuers that provide mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical and surgical benefits. This rule would clarify group health plans and health insurance issuers’ obligations under the MHPAEA and promote compliance with MHPAEA, among other improvements.

Finally, the Department also plans to issue a proposed rule on the Confidentiality of Substance Use Disorder Patient Records. Section 3221 of the CARES Act modifies the statute that establishes protections for the confidentiality of substance use disorder treatment records and directs the Department to work with other federal agencies to update the regulations at 42 CFR part 2 (part 2). As required by the CARES Act, this rule would also be updated to include the increased civil monetary penalties provided in the Bipartisan Budget Act of 2018.

Additionally, the Department will issue a proposed rule entitled Health Information Technology: Updates to the ONC Health IT Certification Program, Establishment of the Trusted Exchange Framework and Common Agreement Attestation Process, and Enhancements to Support Information Sharing. This rule would implement certain provisions of the Cures Act, including the Electronic Health Record (EHR) Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program (Certification Program); a process for health information networks that voluntarily engage in fraud and other misconduct related to HHS grants, contracts, and other agreements. It would also implement Cures Act provisions on information blocking, which authorize the Office of Inspector General (OIG) to investigate claims of information blocking and grant the Department the power to impose civil monetary penalties (CMPs) for information blocking. The Department’s regulations would also be updated to include the information blocking regulations included in the Bipartisan Budget Act of 2018.

Addressing Behavioral Health Needs

The COVID–19 pandemic has made clear that too many Americans have unmet behavioral health needs, which have seen an alarming rise during the pandemic due to illness, grief, job loss, food insecurity, and isolation. The Secretary is committed to addressing the behavioral health effects of the COVID–19 pandemic—including mental health conditions and substance use disorders—especially in underserved communities. This commitment informs the Department’s regulatory priorities over the next year.

The Department is proposing two rules intended to extend telehealth flexibilities for substance use disorder treatments granted during the COVID–19 public health emergency. First, the Department will issue a proposed rule on Nonprescription Drug Product With An Additional Condition for Nonprescription Use. This rule would establish requirements for drug products that could be marketed as nonprescription drug products with an additional condition that a manufacturer must implement to ensure appropriate self-selection or appropriate actual use or both for consumers. The rule is expected to increase consumer access to drug products, which could translate into a reduction in under-treatment of certain diseases and conditions. The Department also plans to issue a proposed rule on Biologics Regulation Modernization, which would update Food and Drug Administration (FDA) biologics regulations to account for the existence of biosimilar and interchangeable biological products. This rule is intended to support competition and enhance consumer choice by preventing efforts to delay or block competition from biosimilars and interchangeable products.

In addition, the Department will issue a proposed rule entitled 340B Drug Pricing Program: Administrative Dispute Resolution. The 340B Drug Pricing Program, which requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net providers, is critical to the ability of safety net providers to stretch scarce federal resources and reach patients with low incomes or without insurance. The rule would establish new requirements and procedures for the Program’s Administrative Dispute Resolution process, making the process more equitable and accessible for participation by program participants. This is intended to replace the previous administration’s rulemaking on the same subject, which was finalized in December 2020.

II. Addressing Health Disparities and Promoting Equity

Equity is the focus of over a dozen Executive Orders issued by President Biden, and it remains a cornerstone of the Biden-Harris Administration’s agenda. The Department recognizes that people of color, people with disabilities, lesbian, gay, bisexual, transgender, and...
Queer (LGBTQ+) people, and other underserved groups in the U.S. have been systematically denied a full and fair opportunity to participate in economic, social, and civic life. Among its other manifestations, this history of inequality shows up as persistent disparities in health outcomes and access to care. As the federal agency responsible for ensuring the health and wellbeing of Americans, the Department under Secretary Becerra’s leadership is committed to tackling these entrenched inequities and their root causes throughout its programs and policies. This regulatory priority includes promoting equity in health care, strengthening health and safety standards for consumer products that impact underserved communities, preventing and combatting discrimination, and ensuring the equitable administration of HHS programs. The Department is also systematically reviewing existing regulations to make certain they adequately address the needs of those most vulnerable to climate change related impacts.

**Promoting Equity in Health Care**

The Department is taking action to promote equity in health care programs and delivery. Earlier this year, the Department finalized a rule on Ensuring Access to Equitable, Affordable, Client-centered, Quality Family Planning Services. This rule revoked the previous administration’s harmful restrictions on the use of Title X family planning funds, which had a disproportionate impact on low-income clients and caused substantial decreases in utilization among clients of color. Revoking the previous rule will allow the Title X service network to expand in size and capacity to provide quality family planning services to more clients.

In addition, the rule updates the Title X regulations to ensure access to equitable, affordable, client-centered, quality family planning services. The Department is also committed to improving the effectiveness of federal health programs that constitute an important source of care for underserved communities. For instance, the Department plans to issue a proposed rule on the Catastrophic Health Emergency Fund (CHEF). CHEF was established to reimburse tribally operated Indian Health Service (IHS) Purchased/Referred Care programs, which serve American Indian/Alaska Native patients, for medical expenses related to high-cost illnesses and events after they have been met. This rule would establish regulations governing CHEF, set the threshold cost that must be reached before CHEF reimbursement can be paid, and establish the procedures for reimbursement under the program.

**Strengthening Health and Safety Standards for Consumer Products That Impact Underserved Communities**

The Department recognizes that people of color, LGBTQ+ people, people with disabilities, people with low incomes, and other underserved populations experience longstanding disparities in leading public health indicators—including obesity and the use of certain tobacco products. To protect the public health and advance equity, the Department is pursuing regulatory action with respect to consumer products that have a disproportionate impact on the health of underserved groups.

For instance, the Department plans to propose two rules on tobacco product standards. First, the Department will issue a proposed rule on Tobacco Product Standard for Menthol in Cigarettes, which would ban menthol as a characterizing flavor in cigarettes. Menthol cigarettes are marketed to and disproportionately used by Black smokers and increase the appeal of smoking for youth and young adults. This standard would reduce the availability of menthol cigarettes. By likely decreasing consumption and increasing the likelihood of cessation, the standard would likely improve the health of current menthol cigarette smokers. Similarly, the Department plans to issue a proposed rule on Tobacco Product Standard for Characterizing Flavors in Cigars. This rule is a tobacco product standard that would ban characterizing flavors—such as strawberry, grape, orange, and cocoa—in all cigars. As with menthol cigarettes, flavored cigars appeal to youth and disproportionately affect underserved communities. This product standard would likely reduce the appeal of cigars, particularly to youth and young adults, and is intended to decrease the likelihood of experimentation, progression to regular use, and the potential for addiction to nicotine.

Furthermore, the Department will issue a proposed rule entitled Nutrient Content Claims, Definition of Term: Healthy. This rule would update the definition for the implied nutrient content claim “healthy” to be consistent with current nutrition science and federal dietary guidelines. This would ensure that foods labeled “healthy” can help consumers improve their diets to help reduce their risk of diet-related chronic disease. This action is necessary to improve the public health and reduce disparities in health outcomes, particularly among people of color and people with low incomes in the U.S., who are disproportionately affected by obesity and diet-related chronic illness.

**Preventing and Remediying Discrimination**

The Department is taking actions to eliminate discrimination as a barrier for historically marginalized communities seeking access to HHS programs and activities. This includes two proposed rules in the Department’s Regulatory Plan for the coming year. First, the Department will issue a proposed rule on Nondiscrimination in Health Programs and Activities, which would make changes to the previous administration’s final rule implementing the nondiscrimination provisions in section 1557 of the ACA. The current section 1557 regulations significantly narrow the scope of section 1557’s protections. Because discrimination in the U.S. health care system is a driver of health disparities, the Section 1557 regulations present a key opportunity for the Department to promote equity and ensure protection of health care as a right. Additionally, the Department will issue a proposed rule entitled Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities. This rule would revise regulations under section 504 of the Rehabilitation Act of 1973 to address unlawful discrimination on the basis of disability in critical HHS-funded health and human services programs. Covered topics include nondiscrimination in life-sustaining care, organ transplantation, suicide prevention services, child welfare programs and services, health care value assessment methodologies, accessible medical equipment, auxiliary aids and services, Crisis Standards of Care and other relevant health and human services activities.

**Ensuring the Equitable Administration of HHS Programs**

Consistent with President Biden’s Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985), the Department is working to embed equity throughout HHS programs and policies, including in the awarding of grants, loans, and procurement contracts.

For instance, the Department plans to issue a proposed rule on the National Institute for Disability, Independent Living, and Rehabilitation Research
Department plans to continue its work on comprehensive strategy to combat COVID–19. Reaching this population is an essential component of the Biden-Harris Administration’s strategy to accelerate our nation’s path out of the pandemic. For this reason, vaccine requirements are one of the Department’s most impactful regulatory options in combatting COVID–19.

Accordingly, the Department has recently issued rules expanding COVID–19 vaccine requirements. For example, the Department issued an interim final rule requiring COVID–19 vaccinations for staff at most Medicare- and Medicaid-participating providers and suppliers.

Additionally, the Department issued an interim final rule with comment period to add new provisions to the Head Start Program Performance Standards to mitigate the spread of the COVID–19 in Head Start programs through COVID–19 vaccine requirements.

Building on these accomplishments, in the coming months, the Department plans to issue an interim final rule that will provide CDC with authority to require individuals entering the U.S. at any port of entry to present proof of vaccination or other proof of immunity against any quarantinable communicable diseases for which the Centers for Disease Control and Prevention (CDC) determines that a public health need exists. This rule will provide CDC with authority to require travelers to be fully vaccinated upon arrival and will reduce the number of international travelers arriving while infected.

Increasing the Resilience of HHS Programs To Deal With COVID–19 and Future Public Health Emergencies

The Department is planning to introduce new flexibilities in HHS programs to minimize disruptions and alleviate burdens that may be caused by COVID–19 or future emergencies. For example, the Department issued a final rule on Flexibility for Head Start Designation Renewals in Certain Emergencies. This rule adds a new provision to the Head Start Program Performance Standards to establish parameters by which the Administration for Children and Families (ACF) may make designation renewal determinations during widespread disasters or emergencies and in the absence of all normally required data.

The Department also plans to issue a proposed rule on Administration for Native Americans (ANA) Non-federal Share Emergency Waivers. The rule will propose the ability for current grantees to request an emergency waiver for the non-federal share match. This update to ANA’s regulation would provide a new provision for recipients to request an emergency waiver in the event of a natural or man-made emergency such as a public health pandemic.

Additionally, the Department issued a proposed rule on Paternity Establishment Percentage Performance Relief. This rule proposes to modify the Paternity Establishment Percentage requirements in child support regulations to provide relief from financial penalties to states impacted by the COVID–19 pandemic. Without regulatory relief, 20 out of the 54 child support programs may be subject to financial penalties associated with their failure to achieve performance for the Paternity Establishment Percentage (PEP) PEP-related financial penalties, which are imposed as reductions in the state’s Temporary Assistance for Needy Families (TANF) program funding, place an undue burden on state budgets and threaten funding that supports the very families who are most in need during this time of crisis.

IV. Boosting the Wellbeing of Children and Families

The Department’s mission to provide effective human services to Americans includes a focus on protecting the wellbeing of children and families. This focus has special significance given the COVID–19 pandemic and its economic consequences, which have deeply affected the lives of children and youth, especially those who are in foster care or otherwise involved in the child welfare system. Secretary Becerra has therefore prioritized children and youth that are in, or candidates for, foster care in the HHS Regulatory Plan.

In support of this priority, the Department will issue a proposed rule to allow Licensing Standards for Relative or Kinship Foster Family Homes that are different from non-relative homes. Currently, in order to claim Title IV–E funding, federal regulations require that all foster family homes meet the same licensing standards, regardless of whether the foster family home is a relative or non-relative placement. The proposed change would address barriers to licensing relatives and kin who can provide continuity and a safe and loving home for children when they cannot be with their parents.
The Department will also issue a proposed rule to reimburse agencies for Title IV–E Administrative Expenditures for Independent Legal Representation in Foster Care and other Related Civil Legal Issues. This rule would make it easier for Title IV–E agencies to achieve permanence faster.

HHS—OFFICE OF THE INSPECTOR GENERAL (OIG)

Final Rule Stage

44. Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking

Priority: Other Significant.
Legal Deadline: None.
Abstract: This proposed rule would revise regulations promulgated in the Social Security Act, the Civil Monetary Penalties Law (42 U.S.C. 1320a-7a), which provides for civil monetary penalty amounts; (2) section 1128A(o)–(s) of the Social Security Act, which provides for civil monetary penalties for fraud and other misconduct related to HHS grants, contracts, and other agreements; and (3) section 3022(b) of the Public Health Service Act (42 U.S.C. 300jj–52), which provides for investigation and enforcement of information blocking.

Alternatives: The regulations incorporate the statutory changes to HHS’ authority found in the Cures Act and the BBA. The alternative would be to rely solely on the statutory authority and not align the regulations accordingly. However, we concluded that the public benefit of providing clarity by placing the new civil monetary penalty amounts in the regulations outweighed any burdens of additional regulations promulgated.

Anticipated Cost and Benefits: We believe that there are no significant costs associated with these proposed revisions that would impose any mandates on State, local, or Tribal governments or the private sector. The regulation will provide a disincentive for bottlenecks to the flow of health data that exist, in part, because parties are reluctant to share data across the healthcare system or prefer not to do so. The final rule will help foster interoperability, thus improving care coordination, access to quality healthcare, and patients’ access to their healthcare data.

Risks: We believe the risks of this regulatory action are minimal because we are relying upon statutory authorities and placing the regulation within our existing regulatory framework.

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.

Government Levels Affected: None.
Agency Contact: Chris Hinkle, Senior Advisor, Department of Health and Human Services, Office of the Inspector General, 330 Independence Avenue SW, Washington, DC 20201, Phone: 202 891–6062, Email: christina.hinkle@oig.hhs.gov.
RIN: 0936–AA09

HHS—OFFICE FOR CIVIL RIGHTS (OCR)

Proposed Rule Stage

45. Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities (Rulemaking Resulting From a Section 610 Review)

Priority: Other Significant.
Unfunded Mandates: Undetermined.
Legal Authority: Sec. 504 of the Rehabilitation Act of 1973 CFR Citation: 45 CFR 84.
Legal Deadline: None.
Abstract: This proposed rule would revise regulations under section 504 of the Rehabilitation Act of 1973 to address unlawful discrimination on the basis of disability in critical HHS-funded health and human services programs. Covered topics include non-discrimination in life-sustaining care, organ transplantation, suicide prevention services, child welfare programs and services, health care value assessment methodologies, accessible medical equipment, auxiliary aids and services, Crisis Standards of Care and other relevant health and human services activities.

Statement of Need: To robustly enforce the prohibition of discrimination on the basis of disability, OCR will update the section 504 of the Rehabilitation Act regulations to clarify obligations and address issues that have emerged in our enforcement experience (including complaints OCR has received), case law, and statutory changes under the Americans with Disabilities Act and other relevant laws, in the forty-plus years since the regulation was promulgated. OCR has heard from complainants and many other stakeholders, as well as federal partners, including the National Council on Disability, on the need for updated regulations in a number of important areas, including non-discrimination in life-sustaining care, organ transplantation, suicide prevention services, child welfare programs and services, health care value assessment methodologies, accessible medical equipment, auxiliary aids and services, Crisis Standards of Care and other
relevant health and human services activities.

Summary of Legal Basis: These regulations are required by law. The current regulations have not been updated to be consistent with the Americans with Disabilities Act, the Americans with Disabilities Amendments Act, or the 1992 Amendments to the Rehabilitation Act, all of which made changes that should be reflected in the HHS section 504 regulations. Under Executive Order 12250, the Department of Justice has provided a template for HHS to update this regulation.

Alternatives: OCR considered issuing guidance, and/or investigating individual complaints and compliance reviews. However, we concluded that not taking regulatory action could result in continued discrimination, inequitable treatment and even untimely deaths of people with disabilities. OCR continues to receive complaints alleging serious acts of disability discrimination each year. While we continue to engage in enforcement, we believe that our enforcement and recipients’ overall compliance with the law will be better supported by the presence of a clearly articulated regulatory framework than continuing the status quo. Continuing to conduct case-by-case investigations without a broader framework risks lack of clarity on the part of providers and violations of section 504 that could have been avoided and may go unaddressed. By issuing a proposed rule, we are undertaking the most efficient and effective means of promoting compliance with section 504.

Anticipated Cost and Benefits: The Department anticipates that this rulemaking will result in significant benefits, namely by providing clear guidance to the covered entity community regarding requirements to administer their health programs and activities in a non-discriminatory manner. In turn, the Department anticipates cost savings as individuals with disabilities can access a range of health care services. The Department expects that the rule, when finalized, will generate some changes in action and behavior that may generate some costs. The rule will address a wide range of issues, with varying impacts and a comprehensive analysis is underway.

Risks: To be determined.

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Regulatory Flexibility Analysis
Required: No.

Government Levels Affected:
Undetermined.

Agency Contact: Molly Burgdorf, Section Chief, Civil Rights Division, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201, Phone: 202 357–3411, Email: ocrmail@hhs.gov.

RIN: 0945–AA15

HHS—OCR

46. Confidentiality of Substance Use Disorder Patient Records

Priority: Other Significant.


CFR Citation: 42 CFR 2; 45 CFR 160; 45 CFR 164.


The CARES Act requires the revisions to regulations with respect to uses and disclosures of information occurring on or after the date that is 12 months after the date of enactment of the Act (March 27, 2021); and not later than one year after the date of enactment, an update to the Notice of Privacy Practices (NPP) provisions of the HIPAA Privacy Rule at 45 CFR 164.520.

Abstract: This rulemaking, to be issued in coordination with the Substance Abuse and Mental Health Services Administration (SAMHSA), would implement provisions of section 3221 of the CARES Act. Section 3221 amended 42 U.S.C. 290dd–2 to better harmonize the 42 CFR part 2 (part 2) confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act.

This rulemaking also would implement the requirement in section 3221 of the CARES Act to modify the HIPAA Privacy Rule NPP provisions so that HIPAA covered entities and part 2 programs provide notice to individuals regarding part 2 records, including patients’ rights and uses and disclosures permitted or required without authorization.

Statement of Need: Rulemaking is needed to implement section 3221 of the CARES Act, which modified the statute that establishes protections for the confidentiality of substance use disorder (SUD) treatment records and authorizes the implementing regulations at 42 CFR part 2 (part 2). As required by the CARES Act, this NPRM proposes regulatory modifications to: (1) Align certain provisions of part 2 with aspects of the HIPAA Privacy, Breach Notification, and Enforcement Rules. (2) Strengthen part 2 protections against uses and disclosures of patients’ SUD records for civil, criminal, administrative, and legislative proceedings. (3) Require that a HIPAA Notice of Privacy Practices address privacy practices with respect to part 2 records.

Summary of Legal Basis: Section 3221(i) of the CARES Act requires rulemaking as may be necessary to implement and enforce section 3221.

Alternatives: HHS considered whether the CARES Act provisions could be implemented through guidance. However, rulemaking is required because the current part 2 regulations are inconsistent with the authorizing statute, as amended by the CARES Act. HHS considered whether to include the anti discrimination provisions of section 3221(g) in this rulemaking. However, because implementation of the anti discrimination provisions implicates numerous civil rights authorities, which require collaboration with the Department of Justice, HHS will address the anti discrimination provisions in a separate rulemaking. HHS considered whether to propose additional changes to part 2 that are not required by section 3221 of the CARES Act. However, adding more proposals would delay publication of the proposed rule and eventual implementation of the CARES Act requirements.

Anticipated Cost and Benefits: HHS estimates that the effects of the proposed requirements for regulated entities would result in new costs of $16,872,779 within 12 months of implementing the final rule. HHS estimates these first-year costs would be partially offset by $11,182,618 of first year cost savings, followed by net savings of $9,612,567 annually in years two through five, resulting in overall net cost savings of $32,760,108 over 5 years.

Risks: To be determined.

Timetable:

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Agency Contact: Marissa Gordon-Nguyen, Senior Advisor for Health Information Privacy Policy, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201.
Phone: 800 368–1019, TDD Phone: 800 537–7697, Email: ocrcivilrights@hhs.gov.
RIN: 0945–AA16

HHS—OCR

47. Nondiscrimination in Health Programs and Activities

Unfunded Mandates: Undetermined.
Legal Authority: Sec. 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116)
CFR Citation: 42 CFR 92.
Legal Deadline: None.
Abstract: This proposed rulemaking would propose changes to the 2020 Final Rule implementing section 1557 of the Patient Protection and Affordable Care Act (PPACA). Section 1557 of PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency, or any entity established under title I of the PPACA.
Statement of Need: The Biden Administration has made advancing health equity a cornerstone of its policy agenda. The current section 1557 implementing regulation significantly curtails the scope of application of section 1557 protections and creates uncertainty and ambiguity as to what constitutes prohibited discrimination in covered health programs and activities. Issuance of a revised section 1557 implementing regulation is important because it would provide clear and concise regulations that protect historically marginalized communities as they seek access to health programs and activities.
Summary of Legal Basis: The Secretary of the Department is statutorily authorized to promulgate regulations to implement section 1557. 42 U.S.C. 18116(c). The current section 1557 Final Rule is pending litigation.
Alternatives: The Department has considered the alternative of maintaining the section 1557 implementing regulation in its current form; however, the Department believes it is appropriate to undertake rulemaking given the Administration’s commitment to advancing equity and access to health care and in light of the issues raised in litigation challenges to the current rule.
Anticipated Cost and Benefits: In enacting section 1557 of the ACA, Congress recognized the benefits of equal access to health services and health insurance that all individuals should have, regardless of their race, color, national origin, sex, age, or disability. The Department anticipates that this rulemaking will result in significant benefits, namely by providing clear guidance to the covered entity community regarding requirements to administer their health programs and activities in a non-discriminatory manner. In turn, the Department anticipates cost savings as individuals are able to access a range of health care services that will result in decreased health disparities among historically marginalized groups and increased health benefits. The Department does not yet have an anticipated cost for this proposed rulemaking; however, it is important to recognize that this NPRM applies pre-existing nondiscrimination requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years.
Risks: To be determined.
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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: Undetermined.
Federalism: Undetermined.
Agency Contact: Dylan Nicole de Kervor, Section Chief, Civil Rights Division, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201.
Phone: 800 368–1019, TDD Phone: 800 537–7697, Email: ocrmail@hhs.gov.
RIN: 0945–AA17

HHS—OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY (ONC)

Proposed Rule Stage

48. ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements To Support Information Sharing

CFR Citation: 45 CFR 170; 45 CFR 171; 45 CFR 172.
Final, Statutory, July 24, 2019, Publish a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement.
Abstract: The rulemaking implements certain provisions of the 21st Century Cures Act, including: the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to real-time benefit tools and electronic prior authorization and potentially other revisions to the Certification Program.
Statement of Need: The rulemaking would implement certain provisions of the 21st Century Cures Act, including: the Electronic Health Record (EHR) Reporting Program condition and maintenance of certification requirements under the (Certification Program); a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rulemaking would also include
proposals for new standards and certification criteria under the Certification Program related to real-time benefit tools and electronic prior authorization. These proposals would fulfill statutory requirements, provide transparency, advance interoperability, and support the access, exchange, and use of electronic health information. Transparency regarding health care information and activities as well as the interoperability and electronic exchange of health information are central to the efforts of the Department of Health and Human Services to enhance and protect the health and well-being of all Americans.

**Summary of Legal Basis:** The provisions would be implemented under the authority of the Public Health Service Act, as amended by the HITECH Act and the 21st Century Cures Act.

**Alternatives:** ONC will consider different options and measures to improve transparency, and the interoperability and access to electronic health information so that the benefits to providers, patients, and payers are maximized and the economic burden to health IT developers, providers, and other stakeholders is minimized.

**Anticipated Cost and Benefits:** The majority of costs for this proposed rule would be incurred by health IT developers in terms of meeting new requirements and continual compliance with the EHR Reporting Program condition and maintenance of certification requirements. We also expect that implementation of new standards and information sharing requirements may also account for some costs. We expect that through implementation and compliance with the regulations, the market (particularly patients, payers, and providers) will benefit greatly from increased transparency, interoperability, and streamlined, lower cost access to electronic health information.

**Risks:** At this time, ONC has not been able to identify any substantial risks that would undermine likely proposals in the proposed rule. ONC will continue to consider and deliberate regarding any identified potential risks and will be sure to identify them for stakeholders and seek comment from stakeholders during the comment period for the proposed rule.

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**HHS—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)**

**Proposed Rule Stage**

49. • Treatment of Opioid Use Disorder With Buprenorphine Utilizing Telehealth

**Priority:** Other Significant. Major under 5 U.S.C. 801.

**Legal Authority:** The Controlled Substances Act, as amended by the Ryan Haight Act (21 U.S.C. 802(54)(G))

**Citation:** 42 CFR 8.11(h).

**Deadline:** None.

**Abstract:** In the face of an escalating overdose crisis and an increasing need to reach remote and underserved communities, extending the buprenorphine telehealth flexibility is of paramount importance. To permanently continue this flexibility among OTPs after the COVID–19 public health emergency ends, SAMHSA proposes to revise OTP regulations under 42 CFR part 8.

**Statement of Need:** This change will help facilitate access to Medications for Opioid Use Disorder (MOUD) in SAMHSA-regulated opioid treatment programs (https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program).

Research details that many patients are unable to regularly access OTPs due to unreliable transportation, geographic disparity, employment or required activities of daily living. Providing buprenorphine via telehealth will allow more patients to receive comprehensive treatment.

**Summary of Legal Basis:** To be determined.

**Alternatives:** In the absence of congressional action, rulemaking is required.

**Anticipated Cost and Benefits:** This change would help facilitate access to and ensure continuity of medication treatment for opioid use disorder in SAMHSA-regulated opioid treatment programs. The change will likely reduce long-term costs at the practice level, while also facilitating access to treatment. However, a minority of providers may face upfront technology costs as they scale-up the provision of treatment via telehealth. We expect that since many providers have now shifted in part to telehealth services during the COVID–19 Public Health Emergency, their costs should now be related to equipment upgrades and software updates. The cost to patients would involve either use of Wi-Fi, data usage with their respective cellular devices or landline telephone service. We expect that many patients already have acquired some of these services, so the cost would be monthly maintenance of such services.

**Risks:** Patients seeking this care might still be required to have an in person visit, as specified by their provider’s plan of care, so to receive comprehensive treatment. Without this provision, there is risk of patients receiving a lower standard of care and increased risk of diversion of the prescribed medications.

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**Regulatory Flexibility Analysis**

**Required:** No.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** Undetermined.

**Agency Contact:** Dr. Neeraj Gandotra, Chief Medical Officer, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 18E67, Rockville, MD 20857, Phone: 202–823–1816, Email: neeraj.gandotra@samhsa.hhs.gov.

**RIN:** 0930–AA38

**HHS—SAMHSA**

50. • Treatment of Opioid Use Disorder With Extended Take Home Doses of Methadone

**Priority:** Economically Significant. Major status under 5 U.S.C. 801 is undetermined.

**Legal Authority:** 21 U.S.C. 823(g)(1)

**Citation:** 42 CFR 8.

**Deadline:** None.

**Abstract:** SAMHSA will revise 42 CFR part 8 to make permanent some regulatory flexibilities for opioid treatment programs to provide extended take home doses of methadone. To facilitate this new treatment paradigm, sections of 42 CFR part 8 will require updating to reflect current treatment
practice. SAMHSA’s changes will impact roughly 1,800 opioid treatment programs and state opioid treatment authorities.

Statement of Need: This change will help enhance accessibility to Medications for Opioid Use Disorder (MOUD) in SAMHSA-regulated opioid treatment programs (https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program). Research and stakeholder feedback details that the take-home flexibilities have been well received by treatment programs and patients. There are very few reports of diversion or overdose, and the provision of extended take-home doses facilitates patient engagement in activities, such as employment, that support recovery. Moreover, those with limited access to transportation benefit from extended take-home doses since they are not required to attend the OTP almost each day of the week to receive Methadone. In this way, making permanent the methadone extended take-home flexibility will facilitate treatment engagement.

Summary of Legal Basis: The current OTP exemption at issue allows OTPs to operate in a manner that is otherwise inconsistent with existing OTP regulations, and therefore, a permanent extension of such exemptions would necessitate revisions of the OTP regulations.

Alternatives: In the absence of congressional action, rulemaking is required.

Anticipated Cost and Benefits: This change will help facilitate and ensure continuity of access to medication treatment for opioid use disorder in SAMHSA-regulated opioid treatment programs. Programs have already incorporated this flexibility into practice and have systems in place that support its delivery in a cost-effective and patient-centered manner. This proposed rule is not expected to impact a cost to patients. In fact, the proposed rule allows patients to engage in employment and necessary daily activities. This supports income generation and also recovery. The increased number of take homes allowed may affect OTP clinic visit and thereby reduce revenue derived from clinical encounters and medication visits. Conversely, patients may experience more convenient engagement with OTPs as the visits to clinic would be decreased.

Risks: Patients seeking this care should still be required to have an in-person visit at the OTP in between provision of take-home doses, as directed by their treating physician’s plan of care. Without this provision, there is risk of patients receiving a lower standard of care and increased risk of diversion of the prescribed medications.

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Regulatory Flexibility Analysis Required: Yes.
Small Entities Affected: Businesses.

Government Levels Affected: State.
Agency Contact: Dr. Neeraj Gandotra, Chief Medical Officer, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 18E67, Rockville, MD 20857, Phone: 202 823–1816, Email: neeraj.gandotra@samhsa.hhs.gov.
RIN: 0930–AA39

HHS—CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Final Rule Stage

51. Requirement for Proof of Vaccination or Other Proof of Immunity Against Quarantinable Communicable Diseases


Legal Authority: secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); sec. 361 to 369, PHS Act, as amended (42 U.S.C. 264 to 272)

CFR Citation: 42 CFR 71.

Legal Deadline: None.

Abstract: This Interim Final Rule (IFR) will amend current regulations to permit CDC to require proof of vaccination or other proof of immunity against quarantinable communicable diseases. When CDC exercises this authority, persons arriving at a U.S. port of entry will be required to provide proof of immunity against quarantinable communicable diseases or proof of having been fully vaccinated against quarantinable communicable diseases. Additionally, as a condition of controlled free practice under 42 CFR 71.31(b), carriers destined for the United States must also comply with requirements of any order issued pursuant to the IFR.

Statement of Need: In response to the COVID-19 pandemic, CDC is amending current regulations to require proof of vaccination or other proof of immunity against quarantinable communicable diseases for persons arriving at a U.S. port of entry.

Summary of Legal Basis: HHS/CDC is promulgating this rule under sections 215 and 311 of the Public Health Service Act, as amended (42 U.S.C. 216, 243); section 361 to 369, PHS Act, as amended (42 U.S.C. 264 to 272).

Alternatives: An alternative considered would allow non-U.S. nationals to submit accurate contact information, complete post-arrival testing, and self-quarantine after arrival in the United States in lieu of the vaccination requirement.

Anticipated Cost and Benefits: HHS/CDC believes it is likely that this rulemaking will be determined to be economically significant under E.O. 12866.

Risks: This rulemaking addresses the risk of introduction of communicable diseases by international travelers into the United States. By implementing this rulemaking, CDC can reduce the risk of importation of new COVID-19 variants into the United States. This rulemaking is expected to increase the number of travelers who are fully vaccinated upon arrival and reduce the number of international travelers arriving while infected.

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Regulatory Flexibility Analysis Required: Undetermined.
Small Entities Affected: Businesses.

Government Levels Affected: Federal, Local, State.
Federalism: Undetermined.

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact: Ashley C. Altenburger JD, Public Health Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS: H 16–4, Atlanta, GA 30307, Phone: 800 232–4636, Email: dgmqpolicyoffice@cdc.gov.
RIN: 0920–AA80

HHS—FOOD AND DRUG ADMINISTRATION (FDA)

Proposed Rule Stage

52. Nonprescription Drug Product With an Additional Condition for Nonprescription Use

Priority: Other Significant.

Unfunded Mandates: Undetermined.

Abstract: The proposed rule is intended to increase access to nonprescription drug products. The proposed rule would establish requirements for a drug product that could be marketed as a nonprescription drug product with an additional condition that an applicant must implement to ensure appropriate self-selection, appropriate actual use, or both by consumers.

Statement of Need: Nonprescription products have traditionally been limited to drugs that can be labeled with information for consumers to safely and appropriately self-select and use the drug product without supervision of a health care provider. There are certain prescription medications that may have comparable risk-benefit profiles to over-the-counter medications in selected populations. However, appropriate consumer selection and use may be difficult to achieve in the nonprescription setting based solely on information included in labeling. FDA is proposing regulations that would establish the requirement for a drug product that could be marketed as a nonprescription drug product with an additional condition that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both by consumers.

Summary of Legal Basis: FDA’s proposed revisions to the regulations regarding labeling and applications for nonprescription drug products labeling are authorized by the FD&C Act (21 U.S.C. 321 et seq.) and by the Public Health Service Act (42 U.S.C. 262 and 264).

Alternatives: FDA evaluated various requirements for new drug applications to assess flexibility of nonprescription drug product design through drug labeling for appropriate self-selection and appropriate use.

Anticipated Cost and Benefits: The benefits of the proposed rule would include increased consumer access to drug products, which could translate to a reduction in under treatment of certain diseases and conditions. Benefits to industry would arise from the flexibility in drug product approval. The proposed rule would impose costs arising from the development of an innovative approach to assist consumers with nonprescription drug product self-selection or use.

Risks: None.

Timetable: None.

Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: Businesses.
Government Levels Affected: None.
Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993, Phone: 301 796–0151, Email: chris.wheeler@fda.hhs.gov.

RIN: 0910–AH62

HHS—FDA

53. Nutrient Content Claims, Definition of Term: Healthy

Priority: Economically Significant.
Major under 5 U.S.C. 801.
CFR Citation: 10 CFR 101.65
(revision).
Legal Deadline: None.
Abstract: The proposed rule would update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. The proposed rule would revise the requirements for when the claim "healthy" can be voluntarily used in the labeling of human food products so that the claim reflects current science and dietary guidelines and helps consumers maintain healthy dietary practices.

Statement of Need: FDA is proposing to redefine "healthy" to make it more consistent with current public health recommendations, including those captured in recent changes to the Nutrition Facts label. The existing definition for "healthy" is based on nutrition recommendations regarding intake of fat, saturated fat, and cholesterol, and specific nutrients Americans were not getting enough of in the early 1990s. Nutrition recommendations have evolved since that time; recommended diets now focus on dietary patterns, which includes getting enough of certain food groups such as fruits, vegetables, low-fat dairy, and whole grains. Chronic diseases, such as heart disease, cancer, and stroke, are the leading causes of death and disability in the United States and diet is a contributing factor to these diseases. Claims on food packages such as "healthy" can provide quick signals to consumers about the healthfulness of a food or beverage, thereby making it easier for busy consumers to make healthy choices.

FDA is proposing to update the existing nutrient content claim definition of "healthy" based on the food groups recommended by the Dietary Guidelines for Americans and also require a food product to be limited in certain nutrients, including saturated fat, sodium, and added sugar, to ensure that foods bearing the claim can help consumers build more healthful diets to help reduce their risk of diet-related chronic disease.

Summary of Legal Basis: FDA is issuing this proposed rule under sections 201(n), 301(a), 403(a), 403(c), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(n), 331(a), 343(a), 343(f), and 371(a)). These sections authorize the agency to adopt regulations that prohibit labeling that bears claims that characterize the level of a nutrient which is of a type required to be declared in nutrition labeling unless the claim is made in accordance with a regulatory definition established by FDA. Pursuant to this authority, FDA issued a regulation defining the "healthy" implied nutrient content claim, which is codified at 21 CFR 101.65. This proposed rule would update the existing definition to be consistent with current federal dietary guidance.

Alternatives:
Alternative 1: Codify the policy in the current enforcement discretion guidance.

In 2016, FDA published “Use of the Term ‘Healthy’ in the Labeling of Human Food Products: Guidance for Industry.” This guidance was intended to advise food manufacturers of FDA’s intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which: (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

One alternative is to codify the policy in this guidance. Although guidance is non-binding, we assume that most packaged food manufacturers are aware of the guidance and, over the past 2 years, have already made any adjustments to their products or product packaging. Therefore, we assume that this alternative would have no costs to industry and no benefits to consumers.

Alternative 2: Extend the compliance date by 1 year.
Extending the anticipated proposed compliance date on the rule updating the definition by 1 year would reduce costs to industry as they would have more time to change products that may be affected by the rule or potentially coordinate label changes with already scheduled label changes. On the other hand, a longer compliance date runs the risk of confusing consumers that may not understand whether a packaged food product labeled “healthy” follows the old definition or the updated one.

**Anticipated Cost and Benefits:** Food products bearing the “healthy” claim currently make up a small percentage (5%) of total packaged foods. Quantified costs to manufacturers include labeling, reformulating, and recordkeeping. Discounted at seven percent over 20 years, the mean present value of costs of the proposed rule is $237 million, with a lower bound estimate of $110 million and an upper bound of $434 million.

Updating the definition of “healthy” to align with current dietary recommendations can help consumers build more healthful diets to help reduce their risk of diet-related chronic diseases. Discounted at seven percent over 20 years, the mean present value of benefits of the proposed rule is $260 million, with a lower bound estimate of $17 million and an upper bound estimate of $700 million.

**Risks:** None.

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**Regulatory Flexibility Analysis**

**Required:** Yes.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** Undetermined.

**Agency Contact:** Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–830), Room 3D–031, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 240 402–1774, Fax: 301 436–1191, Email: vincent.dejesus@fda.hhs.gov.

**RIN:** 0910–A113

**HHS—FDA**

### 54. Biologics Regulation Modernization

**Priority:** Other Significant.

**Legal Authority:** 42 U.S.C. 262; 42 U.S.C. 301, et seq.

**CFR Citation:** 21 CFR 601.

**Legal Deadline:** None.

**Government Levels Affected:** None.

**Federalism:** Undetermined.

**Agency Contact:** Sandra Benton, Senior Policy Coordinator, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 22, Room 1132, Silver Spring, MD 20993, Phone: 301 796–1042, Email: sandra.benton@fda.hhs.gov.

**RIN:** 0910–AI14

**HHS—FDA**

### 55. Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations

**Priority:** Economically Significant.

**Major under 5 U.S.C. 801.**


**CFR Citation:** 21 CFR 800; 21 CFR 801; 21 CFR 808; 21 CFR 874.

**Legal Deadline:** NPRM, Statutory, August 18, 2020.

**Abstract:** FDA is proposing to establish an over-the-counter category of hearing aids to promote the availability of additional kinds of devices that address mild to moderate hearing loss, and proposing related amendments to the current hearing aid regulations, the regulations codifying FDA decisions on State applications for exemption from preemption, and the hearing aid classification regulations.

**Statement of Need:** Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. However, only about one-fifth of people who could benefit from a hearing aid seek intervention. Several barriers likely impede the use of hearing aids, and FDA is proposing rules to address some of these concerns.

**Summary of Legal Basis:** The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.) establishes a comprehensive system for the regulation of devices intended for human use, and hearing aids are subject to those provisions. Furthermore, the FDA Reauthorization Act of 2017 (Pub. L. 115–52, 131 Stat. 1005, 1006) directs FDA to establish by regulation a category of over-the-counter hearing aids. This rulemaking establishes requirements for the safe and effective use of hearing aids, including for the over-the-counter category of hearing aids.
Alternatives: FDA must establish the category of over-the-counter hearing aids as well as requirements that provide for reasonable assurance of safety and effectiveness of these hearing aids. However, FDA will consider different specific options to maximize the health benefits to hearing aid users while minimizing the economic burdens of the final rules.

Anticipated Cost and Benefits: FDA expects benefits of the rule to include cost savings to consumers who wish to buy lower-cost hearing aids, in part by enabling consumers to cross-compare and purchase the devices more easily. Other benefits may include improving health equity, especially for Americans living in rural areas, those with limited mobility, or those with limited means. Individual benefits may include improved health outcomes, and therefore improved social and economic participation. FDA expects costs to include those costs to manufacturers for changing labeling and updating existing processes.

Risks: None.

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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: State.
Federalism: This action may have federalism implications as defined in E.O. 13132.
Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, Phone: 301 796–5678, Email: ian.ostermiller@fda.hhs.gov.
RIN: 0910–AI21

HHS—FDA

56. Tobacco Product Standard for Characterizing Flavors in Cigars


CFR Citation: 21 CFR 1166.

Legal Deadline: None.

Abstract: Evidence shows that flavored tobacco products appeal to youth and also shows that youth may be more likely to initiate tobacco use with such products. Characterizing flavors in cigars, such as strawberry, grape, orange, and cocoa, enhance taste and make them easier to use. Over a half million youth in the United States use flavored cigars, placing these youth at risk for cancer-related disease and death. This proposed rule is a tobacco product standard that would ban characterizing flavors (other than tobacco) in all cigars. We are taking this action with the intention of reducing the tobacco-related death and disease associated with cigar use.

Statement of Need: The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), authorizes FDA to adopt tobacco product standards if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. This product standard would ban characterizing flavors (other than tobacco) in all cigars. Characterizing flavors in cigars, such as strawberry, grape, cocoa, and fruit punch, increase appeal and make the cigars easier to use, particularly among youth and young adults. This product standard would reduce the appeal of cigars, particularly to youth and young adults, and is intended to decrease the likelihood of experimentation, progression to regular use, and potential for addiction to nicotine. In addition, most of the users of flavored cigars are from under served communities and/or at risk populations, including racial/ethnic minorities, lesbian, gay, bisexual, transgender and queer (LGBTQ+) persons, those of lower socioeconomic status, and youth. As such, reducing the appeal and use of cigars by eliminating characterizing flavors is also expected to decrease tobacco-related disparities and promote health equity across population groups.

Summary of Legal Basis: Section 907 of the FD&C Act authorizes the adoption of tobacco product standards if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. Section 907 also authorizes FDA to include in a product standard a provision that restricts the sale and distribution of a tobacco product to the extent that it may be restricted by a regulation under section 906(d) of the FD&C Act. Section 701(a) of the FD&C Act authorizes the promulgation of regulations for the efficient enforcement of the FD&C Act. Alternatives: In addition to the costs and benefits of the proposed rule, FDA will assess the costs and benefits of changing the effective date of the rule, and including pipe tobacco in the proposed standard.

Anticipated Cost and Benefits: The anticipated benefits of the proposed rule stem from diminished exposure to tobacco smoke for users of cigars from decreased experimentation, progression to regular use, and consumption of cigars with characterizing flavors other than tobacco. The diminished exposure and use is expected to reduce illness and improve health.

Risks: None.

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Regulatory Flexibility Analysis
Required: Yes.
Small Entities Affected: Businesses.
Government Levels Affected: Undetermined.
Federalism: Undetermined.
Agency Contact: Samantha LohColladom, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Building 71, Room G335, Silver Spring, MD 20993, Phone: 877 287–1373, Email: ctpregulations@fda.hhs.gov.
RIN: 0910–AI28

HHS—FDA

57. Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies


CFR Citation: 21 CFR 16; 21 CFR 314; 21 CFR 320; 21 CFR 321; 21 CFR 601;

Legal Deadline: None.

Abstract: FDA is proposing to amend 21 CFR 320, in certain parts, and establish a new 21 CFR 321 to clarify FDA’s study conduct expectations for analytical and clinical pharmacology, bioavailability (BA) and bioequivalence (BE) studies that support marketing applications for human drug and biological products. The proposed rule would specify needed basic study conduct requirements to enable FDA to ensure that studies are conducted appropriately and to verify the reliability of study data from those
requirements that applicants and their contractors would need to meet. These proposed requirements are in-line with current industry best practices.

**Risks:** The current regulatory framework does not adequately describe FDA’s expectations for the conduct of clinical pharmacology and clinical and analytical BA and BE studies to ensure industry performs those studies in a consistent and reliable manner. The proposed rule would establish basic study conduct expectations to ensure study reliability, including data reliability and human subject protection.

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**Regulatory Flexibility Analysis Required:** Yes.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** Federal.

**Agency Contact:** Brian Joseph Folian, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5215, Silver Spring, MD 20993–0002. Phone: 240–402–4089, Email: brian.folian@fda.hhs.gov. RIN: 0910–AI57

### HHS–FDA

**58. Tobacco Product Standard for Menthol in Cigarettes**

**Priority:** Economically Significant.

Major status under 5 U.S.C. 801 is undetermined.

**Unfunded Mandates:** Undetermined.

**Legal Authority:** 21 U.S.C. 387g

**CFR Citation:** Not Yet Determined.

**Legal Deadline:** None.

**Abstract:** This proposed rule is a tobacco product standard to prohibit the use of menthol as a characterizing flavor in cigarettes.

**Statement of Need:** The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), authorizes FDA to adopt tobacco product standards under section 907 if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. This product standard would ban menthol as a characterizing flavor in cigarettes. The standard would reduce the availability of menthol cigarettes and thereby decrease the likelihood that nonusers who would experiment with these products would progress to regular cigarette smoking. In addition, among current menthol cigarette smokers, the proposed tobacco product standard is likely to improve the health of current menthol cigarette smokers by decreasing consumption and increasing the likelihood of cessation.

**Summary of Legal Basis:** Section 907 of the FD&C Act authorizes the adoption of tobacco product standards if the Secretary finds that a tobacco product standard is appropriate for the protection of public health.

**Alternatives:** In addition to the costs and benefits of the proposed rule, FDA will assess the costs and benefits of extending the effective date of the rule, creating a process by which some products may apply for an exemption or variance from the proposed product standard, and prohibiting menthol as an additive in cigarette products rather than prohibiting menthol as a characterizing flavor.

**Anticipated Cost and Benefits:** The proposed rule is expected to generate compliance costs on affected entities, such as one-time costs to read and understand the rule and alter manufacturing/importing practices. The quantified benefits of the proposed rule stem from improved health and diminished exposure to tobacco smoke for users of cigarettes from decreased experimentation, progression to regular use, and consumption of menthol cigarettes. The qualitative benefits of the proposed rule include impacts such as reduced illness for smokers.

**Risks:** None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined.

**Government Levels Affected:** Undetermined.

**Federalism:** Undetermined.

**Agency Contact:** Beth Buckler, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, Phone: 877–287–1373, Email: cptregulations@fda.hhs.gov.

RIN: 0910–AI60
59. • 340B Drug Pricing Program; Administrative Dispute Resolution

Priority: Other Significant.
Legal Authority: Not Yet Determined
CFR Citation: 42 CFR 10.
Legal Deadline: None.
Abstract: This proposed rule would replace the Administrative Dispute Resolution (ADR) final rule currently in effect and apply to all drug manufacturers and covered entities that participate in the 340B Drug Pricing Program (340B Program). It would establish new requirements and procedures for the 340B Program’s ADR process. This administrative process would allow covered entities and manufacturers to file claims for specific compliance areas outlined in the statute after good faith efforts have been exhausted by the parties.

Statement of Need: This NPRM proposes to replace the 340B Administrative Dispute Resolution (ADR) final rule, which was published in December 2020 and became effective January 13, 2021. This new rule will propose new requirements and procedures for the 340B Program’s ADR process. The proposed rule applies to drug manufacturers and covered entities participating in the 340B Drug Pricing Program (340B Program) by allowing these entities to file claims for specific compliance areas outlined in the 340B statute after good faith efforts have been exhausted by the parties. This NPRM better aligns with the President’s priorities on drug pricing, better reflects the current state of the 340B Program, and seeks to correct procedural deficiencies in the 340B ADR process.

Summary of Legal Basis: Section 340B(d)(3) of the Public Health Service Act (PHS Act) requires the Secretary to promulgate regulations establishing and implementing an ADR process for certain disputes arising under the 340B Program. Under the 340B statute, the purpose of the ADR process is to resolve (1) Claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHS Act, that a covered entity has violated the prohibition on diversion or duplicate discounts.

Alternative: N/A.
Anticipated Cost and Benefits: N/A.
Risks: None.
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Regulatory Flexibility Analysis

Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Agency Contact: Michelle Herzog, Deputy Director, Office of Pharmacy Affairs, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, 08W12, Rockville, MD 20857, Phone: 301 443-4353, Email: mherzog@hrsa.gov.
RIN: 0906–AB28

HHS—INDIAN HEALTH SERVICE (IHS)

Proposed Rule Stage

60. Catastrophic Health Emergency Fund (CHEF)

Priority: Other Significant.
CFR Citation: Not Yet Determined.
Legal Deadline: None.
Abstract: The Catastrophic Health Emergency Fund (CHEF) pays for extraordinary medical costs associated with treatment of victims of disasters or catastrophic illnesses. CHEF is used to reimburse PRC programs for high cost cases (e.g., burn victims, motor vehicle accidents, high risk obstetrics, cardiology, etc.). The proposed rule establishes conditions and procedures for payment from the fund. During the comment period for the NPRM, several Tribes and Tribal Organizations expressed concern about provisions in the NRPM related to coordination with Tribal self-insurance as an alternate resource. In response to those concerns, the IHS engaged in additional Tribal consultation and decided to delay moving forward with the NPRM pending the resolution of relevant litigation. IHS intends to proceed with developing the NPRM consistent with how Tribal self-insurance is currently recognized in agency policy at https://www.ihs.gov/ihcma/pc/part-2/chapter-3-purchased-refereed-care/. On January 29, 2021, IHS issued a Dear Tribal Leader Letter to clarify that the proposed rule should not be relied upon and that IHS will be moving forward by publishing a new proposed rule in the near future. A copy of the Dear Tribal Leader Letter concerning next steps for the CHEF regulations is available on the IHS website at: https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/2021_Letters/DTLL_01292021.pdf.

Statement of Need: These regulations propose to (1) establish definitions governing CHEF, including definitions of disasters and catastrophic illnesses; (2) establish that a service unit shall not be eligible for reimbursement for the cost of treatment from CHEF until its cost of treating any victim of such catastrophic illness or disaster has reached a certain threshold cost; (3) establish a procedure for reimbursement of the portion of the costs for authorized services that exceed such threshold costs; (4) establish a procedure for payment from CHEF for cases in which the exigencies of the medical circumstances warrant treatment prior to the authorization of such treatment; and (5) establish a procedure that will ensure no payment will be made from CHEF to a service unit to the extent that the provider of services is eligible to receive payment for the treatment from any other Federal, State, local, or private source of reimbursement for which the patient is eligible.

Summary of Legal Basis: Section 202(d) of the Indian Health Care Improvement Act (IHICIA), Public Law 94–437 (1976), as amended by the Patient Protection and Affordable Care Act, Public Law 111–148, section 10221 (2010) requires the Secretary of the Department of Health and Human Services, acting through the Indian Health Service (IHS), to promulgate regulations to implement section 202(d). Section 202(d) of the IHICIA amends the IHS Catastrophic Health Emergency Fund (CHEF) by establishing the CHEF threshold cost to the 2000 level of $19,000; maintains requirements in current law to promulgate regulations consistent with the provisions of the CHEF to establish a definition of disasters and catastrophic illnesses for which the cost of the treatment provided under contract would qualify for payment under CHEF; provides that a service unit shall not be eligible for reimbursement for the cost of treatment from CHEF until its cost of treating any victim of such catastrophic illness or disaster has reached a certain threshold cost which the Secretary shall establish at the 2000 level of $19,000; and for any subsequent year, not less than the threshold cost of the previous year increased by the percentage increase in medical care expenditure category of the consumer price index for all urban consumers; establishes a procedure that will ensure no payment will be made from CHEF to a service unit to the extent that the provider of services is eligible to receive payment for the treatment from any other Federal, State,
local, or private source of reimbursement for which the patient is eligible.

**Alternatives:** None.

**Anticipated Cost and Benefits:** Reducing the threshold to $19,000 will allow for more purchased/referred care cases to be eligible for CHEF. Tribal and Federal PRC programs with limited budgets would have more of an opportunity to access the CHEF.

**Risks:** The increase in cases will deplete the CHEF earlier in the fiscal year unless CHEF funding is increased.

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**Regulatory Flexibility Analysis**

**Required:** No.

**Government Levels Affected:** Undetermined.

**Agency Contact:** CAPT John E. Rael, Director, Office of Resource Access and Partnerships, Department of Health and Human Services, Indian Health Service, 5600 Fishers Lane, Suite 10E73, Rockville, MD 20857, Phone: 301 443–0969, Email: john.rael@ihs.gov.

**RIN:** 0917–AA10

**HHS—IHS**

**Final Rule Stage**

**61. Acquisition Regulations; Buy Indian Act; Procedures for Contracting**

**Priority:** Other Significant.

**Legal Authority:** Transfer Act of 1954 (42 U.S.C. 2001 et seq.); Transfer Act (42 U.S.C. 2001); Buy Indian Act 1910; Indian Community Economic Enhancement Act of 2020 (Pub. L. 116–261); . . . 42 CFR Citation: Not Yet Determined.

**Legal Deadline:** None.

**Abstract:** The Indian Health Service (IHS) is proposing to issue regulations guiding implementation of the Buy Indian Act, which provides IHS with authority to set-aside procurement contracts for Indian-owned and controlled businesses. This rule supplements the Federal Acquisition Regulation (FAR) and the current HHS Acquisition Regulations (HSAR). IHS may use the Buy Indian Act procurement authority for acquisitions in connection with those functions. This rule is proposed to describe administration procedures that the IHS will use in all of its locations to encourage procurement relationships with eligible Indian Economic Enterprises in the execution of the Buy Indian Act. These proposed rules are intended to be consistent with Buy Indian Act rules previously promulgated by the Department of Interior, IHS published the proposed rule on November 10, 2020, with a 60-day comment period ending January 11, 2021 (85 FR 71596). Comments were received from tribes and tribal entities requesting an extension of the comment period due to the encompassing of the holiday season during the original comment period, as well as the disproportionately high impact of the pandemic on Indian Country. Both of these events delayed stakeholders from being able to perform a complete and full review and provide comments within the initial 60-day comment period. On April 21, 2021, HHS reopened the NPRM and extended the comment period for 60 days. The comment period closed on June 21, 2021.

**Statement of Need:** Due to the unique legal and political relationship with Indian Tribes, the Federal government has a number of programs and authorities to support and expand the economic development of tribal entities and their individual members. The Buy Indian Act of 1910 is one of these programs that allows for the Department of Health and Human Services’ IHS and the Department of the Interior’s BIA to award federal contracts to Indian-owned businesses without using the standard competitive process. The IHS annually obligates over $1 billion in commercial contracts. Much of this can be set-aside under the Buy Indian Act. The established use of this rule will promote the growth and development of Indian industries and in turn, foster economic development and sustainability in Indian Country.

**Summary of Legal Basis:** This rule proposes to amend the HSAR, which is maintained by Assistant Secretary for Financial Resources (ASFR) pursuant to 48 CFR 301.103, to establish Buy Indian Act acquisition policies and procedures for IHS that are consistent with rules proposed and/or adopted by the Department of the Interior. This rule is to provide uniform administration procedures that the IHS will use in all of its locations to encourage procurement relationships with Indian labor and industry in the execution of the Buy Indian Act. IHS’ current rules are codified at HSAR, 48 CFR part 326, subpart 326.6. The Transfer Act authorizes the Secretary of HHS to make such other regulations as he deems desirable to carry out the provisions of the [Transfer Act]. 42 U.S.C. 2001. The Secretary’s authority to carry out functions under the Transfer Act has been vested in the Director of the Indian Health Service under 25 U.S.C. 1661. Because of these authorities, use of the Buy Indian Act is reserved to IHS and is not available for use by any other HHS component. IHS authority to use the Buy Indian Act is further governed by 25 U.S.C. 1633, which directs the Secretary to issue regulations governing the application of the Buy Indian Act to construction activities. Additionally, when Congress amended the Buy Indian Act, they added a requirement to harmonize the Buy Indian Act regulations. As such, the Secretaries shall promulgate regulations to harmonize the procurement procedures of the Department of the Interior and the Department of Health and Human Services, to the maximum extent practicable.

**Alternatives:** There are no apparent alternatives to ensure compliance with this law.

**Anticipated Cost and Benefits:** The benefits of this rule include, policy and compliance objectives such as: Supporting procurement relationships with Indian labor and industry as well as overall Tribal relationships, the execution of the Buy Indian Act; consistent IHS use with the DOI/BIA regulations; and fostering economic development and sustainability in Indian Country. To avoid additional costs, the rule supports utilization of fair and reasonable price requirements, pursuant to the Federal Acquisition Regulations (FAR). Additionally, IHS intends to conduct all training on the Buy Indian Act in-house and/or in collaboration with the DOI/BIA.

**Risks:** IHS foresees minimal risks in the implementation of this rule. One potential risk is an increased number of Buy Indian Act challenges to representation requirement but IHS views this more as a benefit in ensuring Buy Indian Act set-aside commercial contracts are appropriately awarded to confirmed Indian Economic Enterprises.

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**Regulatory Flexibility Analysis**

**Required:** Undetermined.
HHS—CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

Proposed Rule Stage

62. Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes (CMS–2421)

**Priority:** Economically Significant. Major under 5 U.S.C. 801.

**Legal Authority:** 42 U.S.C. 1302

**CFR Citation:** 42 CFR 431; 42 CFR 435; 42 CFR 457.

**Legal Deadline:** None.

**Abstract:** This proposed rule would streamline eligibility and enrollment processes for all Medicaid and CHIP populations and create new enrollment pathways to maximize enrollment and retention of eligible individuals.

**Statement of Need:** Since the implementation of the Affordable Care Act (ACA), CMS has made improvements in streamlining the Medicaid and CHIP application, eligibility determination, enrollment, and renewal processes. Simplifying enrollment in Medicaid and CHIP coverage is a foundational step in efforts to address health disparities for low-income individuals. However, gaps remain in States’ ability to seamlessly process beneficiaries’ eligibility and enrollment in order to maximize coverage. This proposed rule will provide States with the tools they need to reduce unnecessary barriers to enrollment in Medicaid and CHIP and to keep eligible beneficiaries covered.

**Summary of Legal Basis:** This rule responds to the January 28, 2021, Executive Order on Strengthening Medicaid and the Affordable Care Act. It addresses components of title XIX and title XXI of the Social Security Act and several sections of the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act.

**Alternatives:** In developing the policies contained in this rule, we considered numerous alternatives to the presented proposals, including maintaining existing requirements. These alternatives will be described in the rule.

**Anticipated Cost and Benefits:** The provisions in this rule would streamline Medicaid and CHIP enrollment processes and ensure that eligible beneficiaries can maintain coverage. While states and the Federal Government may incur some initial costs to implement these changes, this rule aims to reduce administrative barriers to enrollment, which is expected to reduce administrative costs over time. The provisions in this rule are designed to increase access to affordable health coverage, and we believe that the benefits will justify any costs. Additionally, through clear and consistent requirements for the timely renewal of eligibility for all beneficiaries, this rule promotes program integrity, thereby protecting taxpayer funds at both the state and federal levels. As we move toward publication, estimates of the cost and benefits of these provisions will be included in the rule.

**Risks:** We anticipate that the provisions of this rule would further the administration’s goal of strengthening Medicaid and making high-quality health care accessible and affordable for every American. At the same time, through clear and consistent requirements for conducting regular renewals of eligibility, acting on changes reported by beneficiaries and maintaining thorough recordkeeping on these activities, this rule would reduce the risk of improper payments.

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**Regulatory Flexibility Analysis Required:** Undetermined.

**Government Levels Affected:** Federal, State.

**Federalism:** Undetermined.

**Agency Contact:** Lindsey Murtagh, Director, Market-Wide Regulation, Division, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 301 492–4106, Email: lindsey.murtagh@cms.hhs.gov.

**RIN:** 0938–AU64

**HHS—CMS**

63. Provider Nondiscrimination Requirements for Group Health Plans and Health Insurance Issuers in the Group and Individual Markets (CMS–9910)

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Legal Authority:** Pub. L. 116–260, Division BB, title I; 42 U.S.C. 300gg–5(a) CFR Citation: Not Yet Determined.

**Legal Deadline:** NPRM, Statutory, January 1, 2022, Section 108 of the No Surprises Act requires proposed rulemaking by January 1, 2022.

**Abstract:** This proposed rule would implement section 108 of the No Surprises Act.

**Statement of Need:** Not yet determined.

**Summary of Legal Basis:** The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2793, 2791, 2792, 2794, 2790A–1 through 2790B–9 of the PHS Act (42 U.S.C. 300gg–63, 300gg–91, 300gg–92, 300gg–94, 300gg–139), as amended.

**Alternatives:** Not yet determined.

**Anticipated Cost and Benefits:** Not yet determined.

**Risks:** Not yet determined.

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**Regulatory Flexibility Analysis Required:** Undetermined.

**Government Levels Affected:** Federal, State.

**Federalism:** Undetermined.

**Agency Contact:** Lindsey Murtagh, Director, Market-Wide Regulation, Division, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 301 492–4106, Email: lindsey.murtagh@cms.hhs.gov.

**RIN:** 0938–AU64

**HHS—CMS**

64. Assuring Access to Medicaid Services (CMS–2442)

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Legal Authority:** 42 U.S.C. 1302

**CFR Citation:** 42 CFR 438; 42 CFR 447.
Legal Deadline: None.

Abstract: This rule proposes to assure and monitor equitable access in Medicaid and the Children’s Health Insurance Program (CHIP). These activities could include actions that support the implementation of a comprehensive access strategy as well as payment specific requirements related to particular delivery systems.

Statement of Need: In order to assure equitable access to health care for all Medicaid and Children’s Health Insurance Program (CHIP) beneficiaries across all delivery systems, access regulations need to be multi-factorial and focus beyond payment rates. Barriers to accessing health care services can be as heterogeneous as Medicaid and CHIP populations ranging from potential barriers to access which can be measured through provider availability and provider accessibility - to-realized or perceived access barriers which can be measured through utilization and satisfaction with services. CMCS is developing an access strategy that will address not only Fee-For-Service (FFS) payment, but also access in managed care and Home and Community-Based Services (HCBS). The scope of this rule is unknown at this time, but will seek to assure and monitor equitable access in Medicaid and CHIP.

Summary of Legal Basis: At this time, the scope of the rule is unknown. However, there are no broad access requirements specified in the statute beyond payment: Section 1902(a)(30)(A) of the Act requires states to “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.”

Alternatives: In developing the policies contained in this rule, we will consider numerous alternatives to the proposed proposals, including maintaining existing requirements. These alternatives will be described in the rule.

Anticipated Cost and Benefits: This proposed rule would be expected to result in potential costs for states to come into and remain in compliance. Estimates for associated costs are unknown at this time and may vary by state. Information about anticipated costs will be included in the proposed rule.

Risks: At this time, we are still at work developing a comprehensive access strategy. We have not yet concluded which pieces are best done through rulemaking versus other guidance.

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Regulatory Flexibility Analysis Required: No.

Government Levels Affected: State.

Agency Contact: Karen Llanos, Director, Medicaid Innovation Accelerator Program and Strategy Support, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and CHIP Services, MS: S2–04–28, 7500 Security Boulevard, Baltimore, MD 21244. Phone: 410 786–9071. Email: karen.llanos@cms.hhs.gov. RIN: 0938–AU68

HHS—CMS

65. Implementing Certain Provisions of the Consolidated Appropriations Act and Other Revisions to Medicare Enrollment and Eligibility Rules (CMS–4199)


Legal Authority: Pub. L. 116–260, secs. 120 & 402; 42 U.S.C 1395i–2 CFR Citation: 42 CFR 400; 42 CFR 406; 42 CFR 407; 42 CFR 408; . .

Legal Deadline: Final, Statutory, October 1, 2022, Enrollments under section 402 of the CAA start on 10/1/22. Final, Statutory, January 1, 2023, Provisions under sections 120 and 402 of the CAA must be effective 1/1/23.

Abstract: This proposed rule would implement certain Medicare-related provisions of the Consolidated Appropriations Act, 2021 (CAA). Specifically, section 120 of the CAA allows for Medicare coverage to take effect earlier for people who enroll in the General Enrollment Period (GEP) or within the last three months of their Initial Enrollment Period (IEP). Section 120 also gives the Secretary the authority to establish special enrollment periods for exceptional circumstances. Section 402 of the CAA extends immunosuppressive drug coverage for Medicare kidney transplant recipients beyond the current law 36-month limit following a transplant by providing immunosuppressive drug coverage under Medicare Part B for these individuals. Separately, this rule would address enrollment in Medicare Part A for applicants who are eligible for Social Security benefits, but are not yet receiving them, and make certain updates related to state payment of Medicare premiums.

Statement of Need: This rule is necessary to implement section 120 of the Consolidated Appropriations Act, 2021 (CAA) that revises effective dates of coverage for individuals enrolling in Medicare and gives the Secretary of the Department of Health and Human Services the authority to establish special enrollment periods (SEPs) for exceptional circumstances beginning January 1, 2023. This rule also implements section 402 of the CAA that, beginning January 1, 2023, provides for coverage of immunosuppressive drugs under part B for certain individuals whose Medicare entitlement based on end-stage renal disease (ESRD) would otherwise end 36-months after the month in which they received a successful kidney transplant.

Summary of Legal Basis: The legal basis of this rule is the Consolidated Appropriations Act, 2021 (sections 120 and 402).

Alternatives: The provisions of this rule are primarily established in statute. Where there is discretion, alternatives will be discussed within the text of the rule. Public comments will also be considered in the development of the final rule.

Anticipated Cost and Benefits: We believe that this rule will have a positive impact on health outcomes of beneficiaries because it provides for Medicare coverage to begin earlier and provides for coverage of immunosuppressive drugs in situations where, currently, they are not covered.

Risks: The risks associated with not publishing this regulation would be not establishing the regulatory authority under which immunosuppressive drug benefits and effective dates of coverage will be based upon beginning January 2023.

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Regulatory Flexibility Analysis Required: Undetermined.

Government Levels Affected: None.

Agency Contact: Kristy Nishimoto, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: 100, 7500 Security Boulevard, Baltimore, MD 21244. Phone: 206 615–2367. Email: kristy.nishimoto@cms.hhs.gov. RIN: 0938–AU85
66. • Requirements for Rural Emergency Hospitals (CMS–3419) (Section 610 Review)


Unfunded Mandates: Undetermined.

Legal Authority: 42 U.S.C. 1395x

CPR Citation: Not Yet Determined.

Legal Deadline: Final, Statutory, January 1, 2023. Per statute, amendments made by this section apply to items and services furnished on or after January 1, 2023.

Abstract: This proposed rule would establish health and safety requirements for a new provider type, Rural Emergency Hospitals, in accordance with section 125 of the Consolidated Appropriations Act, 2021.

Summary of Legal Basis: This rule addresses section 125 of the Consolidated Appropriations Act, 2021. We understand that the amendments made by this section apply after January 1, 2023. Per statute, amendments made by this section apply to items and services furnished on or after January 1, 2023.

Alternatives: We understand that the policies that will be included in this proposed rule will have impacts on rural communities and providers of health care services in these communities. These impacts will be taken into consideration as we evaluate policy alternatives in the development of this proposed rule. These alternatives will be included in the rule.

Anticipated Cost and Benefits: This proposed rule aims to increase access to health care services, including emergency services, to rural communities. Many rural Americans face healthcare inequities resulting in worse outcomes overall in rural areas. Increasing access to key health care services in these communities will help address such healthcare inequities. Estimates of the cost and benefits of the developed provisions will be included in the proposed rule.

Risks: Although there are some risks associated with the potential loss of inpatient services in rural communities as providers convert to an REH, we anticipate that only eligible rural hospitals and critical access hospitals with very low average daily inpatient censuses will convert to an REH. We anticipate that the provisions of this proposed rule would help further HHS’s goal of increasing rural access to care.

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67. • Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021 (CMS–9903)


CPR Citation: Not Yet Determined.

Legal Deadline: None.

Abstract: This rule would propose amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under title I of the Patient Protection and Affordable Care Act.

Statement of Need: Not yet determined.

Summary of Legal Basis: The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792, 2794, 2799A–1 through 2799B–9 of the PHS Act (42 U.S.C. 300gg–63, 300gg–91, 300gg–92, 300gg–94, 300gg–139), as amended.

Alternatives: Not yet determined.

Anticipated Cost and Benefits: Not yet determined.

Risks: Not yet determined.

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Medicaid Services, Center for Consumer Information and Insurance Oversight, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 301 492–4106, Email: lindsey.murtagh@cms.hhs.gov. RIN: 0938–AU94

HHS—CMS

Final Rule Stage

69. • Omnibus COVID–19 Health Care Staff Vaccination (CMS–3415) (Section 610 Review)


Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

CFR Citation: 42 CFR 483.

Legal Deadline: None.

Abstract: This interim final rule with comment period revises the infection control requirements that most Medicare- and Medicaid-participating providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of residents, clients, patients, and staff and reflect lessons learned as result of the COVID–19 public health emergency. The revisions to the infection control requirements establish COVID–19 vaccination requirements for staff at the included Medicare- and Medicaid-participating providers and suppliers. These changes are necessary to protect the health and safety of residents, clients, patients, and staff.

Summary of Legal Basis: CMS has broad statutory authority to establish health and safety regulations, which includes authority to establish health and safety standards for Medicare and Medicaid certified facilities. We believe requiring staff vaccinations for COVID–19 is critical to safeguarding the health and safety of all individuals seeking health care in Medicare and Medicaid certified facilities. Sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under this Act.

Alternative: In developing the policies contained in this rule, we considered numerous alternatives to the final provisions including limiting vaccination requirements to direct care employees, additional requirements, and different implementation time frames. These alternatives are discussed in further detail in the rule.

Anticipated Cost and Benefits: We estimate costs associated with this rulemaking including those costs associated with information collection requirements, additional recordkeeping, and costs associated with vaccination. We anticipate benefits of the rule to include reduction in the transmission of infections and decreases in hospitalizations and mortality.

Risks: Although there is some uncertainty about the effects of this rule on health care staffing, we believe that the wide application of these requirements will reduce the likelihood of individual workers seeking new employment in order to avoid vaccination.

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Regulatory Flexibility Analysis

Required: Yes.

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations.

Government Levels Affected: Federal, Local, State.

Federalism: This action may have federalism implications as defined in E.O. 13132.

Agency Contact: Kim Roche, Nurse, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: C2–21–16, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–3524, Email: kim.roche@cms.hhs.gov.

RIN: 0938–AU75

HHS—ADMINISTRATION FOR CHILDREN AND FAMILIES (ACF)

Proposed Rule Stage

70. Native Hawaiian Revolving Loan Fund Eligibility Requirements

Priority: Other Significant.

Legal Authority: 42 U.S.C. 2991

CFR Citation: 45 CFR 1336.

Legal Deadline: None.

Abstract: This regulation proposes to reduce the required Native Hawaiian ownership or control for an eligible applicant to the Native Hawaiian Revolving Loan Fund program under 45 CFR 1336.62.

Statement of Need: The Native Hawaiian Revolving Loan Fund (NHRLF) was established to provide loans and loan guarantees to Native Hawaiians who are unable to obtain loans from private sources on reasonable terms and conditions for the purpose of promoting economic development in the State of Hawaii. Since many Native Hawaiians reside on leasehold interests that cannot be collateralized (Hawaiian Homelands), the NHRLF serves as an important lender of last resort for Native Hawaiian borrowers. Applicants for an NHRLF loan must be an individual Native Hawaiian or a 100 percent Native Hawaiian owned organization. To qualify for an NHRLF loan when one spouse is not Native Hawaiian, Native Hawaiian borrowers must establish or reorganize their business’ legal structure to exclude a non-Native Hawaiian spouse from ownership. As the 100 percent Native Hawaiian ownership requirement prevents many Native Hawaiian family-owned businesses and families from obtaining a loan, the Administration for Children and Families (ACF) proposes to reduce the eligibility requirement to maximize loan funds and spur further economic development. This proposed change will likely increase the applicant pool and availability of loan proceeds to small Native Hawaiian-owned businesses and families whose credit would be deemed too risky for traditional lenders as businesses recover from the COVID–19 pandemic. As a lender of last resort, this revolving loan fund has filled and will continue to fill a unique credit niche for Native Hawaiian-owned businesses.

Summary of Legal Basis: This NPRM is under the authority granted by section 803A of Native Americans Programs Act. That section directed ACF’s Administration for Native Americans (ANA) to develop the regulations that set forth the procedures and criteria for making loans under the NHRLF. Section 803A also permitted the ANA Commissioner to prescribe any other regulations that the Commissioner determines are necessary to carry out the purposes of NHRLF.

Alternative: ACF reviewed alternatives to providing greater flexibility to NHRLF applicants that directly respond to barriers for accessing loans and other viable options were not identified.

Anticipated Cost and Benefits: ANA does not provide loans directly to entities but does so through the regulated entity, the State of Hawaii’s
Office of Hawaiian Affairs. The rule does not create additional requirements but provides flexibility by expanding eligibility and availability of loan proceeds to small entities.

Risks: It is possible that this proposed change will increase business loan demand. There is also the possibility that businesses may act strategically to qualify for NHLRF loans by adding Native Hawaiian ownership. This restructuring may still benefit Native Hawaiians as more Native Hawaiians could become business partners with non-Native Hawaiians. Expansion of the program to more Native Hawaiian families is consistent with the policy goal of the statute which is promoting economic development among Native Hawaiians in Hawaii.

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HHS—ACF

71. Paternity Establishment Percentage Performance Relief

Priority: Other Significant.

Legal Authority: Sec. 1102 of the Social Security Act

CFR Citation: 45 CFR 305.

Legal Deadline: None.

Abstract: This regulation proposes to modify the Paternity Establishment Percentage performance requirements in child support regulations under 45 CFR part 305, to provide relief from financial penalties to states impacted by the COVID–19 pandemic.

Statement of Need: The COVID–19 pandemic had a debilitating effect on state child support programs, disrupting administrative and judicial operations and limiting states’ ability to provide services and maintain performance. Without regulatory relief, 20 out of the 54 child support programs (title IV–D under the Act) will be subject to financial penalties associated with their failure to achieve performance for the Paternity Establishment Percentage (PEP) described in section 409(a)(8) and 452(g) of the Social Security Act (the Act) and child support regulations under 45 CFR part 305. PEP-related financial penalties, which are imposed as reductions in the state’s Temporary Assistance for Needy Families (TANF) program funding, place an undue burden on state budgets and threaten funding that supports the very families who are most in need during this time of crisis.

Summary of Legal Basis: This proposed rule is published under the authority granted to the Secretary of Health and Human Services by section 1102 of the Social Security Act (the Act) (42 U.S.C. 1302). Section 1102 of the Act authorizes the Secretary to publish regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is responsible under the Act. The proposed relief from the Paternity Establishment Percentage performance penalty under this NPRM is based on statutory authority granted under section 452(g)(3)(A) of the Act (42 U.S.C. 652(g)(3)(A)).

Alternatives: Because PEP performance measures and penalties are required by statute and regulation, relief can only be provided through regulation or legislation. The PEP performance requirement is established under 452(g) of the Social Security Act and 45 CFR 305.40. Section 452(a)(4)(C)(i) of the Act requires the Secretary to determine whether State-reported data used to determine the performance levels are complete and reliable. Additionally, section 409(a)(8)(A) of the Act and 45 CFR 305.61(a)(1) provides for a financial penalty if there is a failure to achieve the required level of performance or an audit determines that the data is incomplete or unreliable.

Anticipated Cost and Benefits: This proposed rule, if finalized, will ensure that penalties are not imposed against a state’s TANF grant, during a time when public assistance funds are critically needed. The financial penalties against states are estimated at $3.5 million of penalties for 3 states that did not meet PEP performance levels in FY 2019 and $83 million for 18 states that did not meet performance levels in FY 2020 and FY 2021 PEP.

Risks: To be determined.

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Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Legal Authority: 42 U.S.C. 2991

CFR Citation: 45 CFR 1336.

Legal Deadline: None.

Abstract: This regulation proposes to streamline the process for Administration for Native Americans (ANA) grant program applicants to request a waiver for non-federal share for the 20 percent match required by statute for ANA grants. The regulation will also propose the ability for current grantees to request an emergency waiver for the non-federal share match.

Statement of Need: The Native American Programs Act of 1974, as amended, (NAPA) requires projects awarded funding through sections 803, 804, and 805 provide a 20 percent match of the total cost of the project, unless a waiver is obtained through objective criteria as outlined in ANA’s regulations. The current regulations outline the requirements and criteria for applicants to request a waiver for non-federal share (NFS) at 45 CFR part 1336.50 at time of application for a new or continuation award. The COVID–19 pandemic had a detrimental impact on the economies and financial resources of ANA’s Native American recipients, most of whom had to close their borders to protect their citizens. Many tribal enterprises were forced to close, and tourism revenues became non-existent. Partnerships and vendors were no longer able to contribute previously committed resources for NFS. During this time, many recipients grew concerned that they would be unable to fully meet their NFS of their grant award. ANA explored the possibility of providing emergency NFS waivers to ANA grantees. Unfortunately, ANA learned that it does not currently have the authority to issue emergency NFS waivers, as neither emergency waiver authority nor a process to approve such
requests exists in ANA’s regulations. Current regulations require waiver requests to be submitted at the time of application or during the non-compete continuation process. This request to update ANA’s regulation would provide a new provision for recipients to request an emergency NFS waiver in the event of a natural or man-made emergency such as a public health pandemic.

Summary of Legal Basis: The Native American Programs Act of 1974, as amended (NAPA) requires projects awarded funding through sections 803, 804, and 805 provide a 20 percent match of the cost of the project, unless a waiver is obtained through objective criteria as outlined in ANA’s regulations. Current regulations outline the requirements and criteria to request a waiver at 45 CFR part 1336.50 at time of application for a new or continuation award. However, there is no existing regulations or criteria to provide an emergency waiver for NFS to recipients experience a natural or man-made disaster or public health emergency such as COVID–19.

Alternatives: The alternative would be to not offer the emergency waiver. Anticipated Cost and Benefits: There are no known costs to the program by issuing this rule. Benefits—This proposed rule is responsive to the President’s Executive Order 13995: Ensuring an Equitable Pandemic Response and Recovery and the Executive Order on Economic Relief Related to the COVID–19 Pandemic and also responsive to the needs of Native American communities. Existing regulations states that ANA must determine that approval of an NFS waiver will not prevent the award of other grants at levels it believes are desirable for the purposes of the program. Approval of this emergency waiver regulation will also decrease the potential audit findings of entities not meeting the required NFS. In addition, it reduces further harm to recipients who are impacted by an emergency situation which caused unforeseen and additional financial hardships.

Risks: There are no known risks to the program by issuing this rule.

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Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Agency Contact: Mirtha Beadle, Senior Policy Advisor, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW, Washington, DC 20201, Phone: 202 401–6506, Email: mirtha.beadle@acf.hhs.gov.

RIN: 0970–AC88

HHS—ACF

73. Foster Care Legal Representation


Legal Authority: Sec. 474(a)(3) of the Social Security Act; sec. 1102 of the Social Security Act

CFR Citation: 45 CFR 1356.60(c).

Legal Deadline: None.

Abstract: This regulation proposes to allow a title IV–E agency to claim Federal financial participation for the administrative cost of providing independent legal representation to a child who is either a candidate for foster care or in foster care, and his/her parent to prepare for and participate in judicial determinations in foster care and other related civil legal proceedings.

Statement of Need: Allowing title IV–E agencies to claim Federal reimbursement for independent legal representation in legal proceedings that are necessary to carry out the requirements in the agency’s title IV–E plan, including civil proceedings, may help prevent the need to remove a child from the home or, for a child in foster care, achieve permanence faster. Research demonstrates that some of the circumstances bringing families into contact with the child welfare system (poverty, educational neglect, inadequate housing, failure to provide adequate nutrition, and failure to safeguard mental health due to domestic violence) can be addressed before a child enters foster care by providing legal representation early in foster care legal proceedings and in civil legal matters. When children are removed from the home, studies show having access to legal representation for civil legal issues earlier in a case can improve the rate of reunification, nearly double the speed to legal guardianship or adoption, and result in more permanent outcomes for children and families.

Summary of Legal Basis: Section 474(a)(3) of the Act authorizes Federal reimbursement for title IV–E administrative costs, which are defined as costs found necessary by the Secretary for the provision of child placement services and for the proper and efficient administration of the State [title IV–E] plan. Section 1102 of the Act authorizes the Secretary to publish regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is responsible under the Act.

Alternatives: If this NPRM is not published, agencies may continue to claim FFPP for administrative costs of independent legal representation provided by attorneys representing children in title IV–E foster care, children who are candidates for title IV–E foster care, and the child’s parents in all stages of foster care legal proceedings (Child Welfare Policy Manual (CWPM) 8.1B #30, 31 and 32).

Anticipated Cost and Benefits: This final rule impacts state and tribal title IV–E (child welfare) agencies. ACF estimates that the proposed regulatory change would cost the federal government $141 million in FFPP per year within 5 years of implementation. This proposal does not impose a burden or cost on the title IV–E agency. The title IV–E agency has discretion to provide allowable independent legal representation to families.

Risks: None.

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Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: None.

Government Levels Affected: None.

Agency Contact: Kathleen McHugh, Director, Division of Policy, Children’s Bureau, ACYF/ACF/HHS, Department of Health and Human Services, Administration for Children and Families, 370 L’Enfant Promenade SW, Washington, DC 20447, Phone: 202 401–5789, Fax: 202 205–8221, Email: kmchugh@acf.hhs.gov.

RIN: 0970–AC89

HHS—ACF

74. Separate Licensing Standards for Relative or Kinship Foster Family Homes

Priority: Other Significant.


CFR Citation: 45 CFR 1355.20.

Legal Deadline: None.

Abstract: This regulation proposes to allow title IV–E agencies to adopt separate licensing standards for relative or kinship foster family homes.

Statement of Need: Currently, the regulation provides that in order to claim title IV–E, all foster family homes must meet the same licensing standards, regardless of whether the foster family
HHS—ADMINISTRATION FOR COMMUNITY LIVING (ACL)

Proposed Rule Stage

75. National Institute for Disability, Independent Living, and Rehabilitation Research Notice of Proposed Rulemaking

Priority: Other Significant.

Legal Authority: 29 U.S.C. 29—Labor; Chapter 16—Vocational Rehabilitation and Other Rehabilitation Services Subchapter II—Research and Training; sec. 762—National Institute on Disability, Independent Living, and Rehabilitation Research

CPR Citation: 45 CFR 1330.24.

Legal Deadline: None.

Abstract: The proposed rule will amend subsection 24 of the National Institute for Disability, Independent Living and Rehabilitation Research (NIDILRR) regulation (45 CFR 1330.24), which would make revisions to advance equity in the peer review criteria that NIDILRR uses to evaluate disability research applications across all of its research programs, as well as emphasize the need for engineering research and development activities within NIDILRR’s Rehabilitation Engineering Research Centers (RERC) program.

Statement of Need: There is a need for increased representation of people with disabilities among the research teams of NIDILRR grantees to help ensure rigor and relevance of sponsored research. There is a separate need for increased emphasis on engineering R&D in NIDILRR’s Rehabilitation Engineering Research Centers program.

Summary of Legal Basis: (1) An update of 45 CFR 1330.24 will strengthen NIDILRR’s ability to meet goals described in the Executive Orders on Advancing Equity. Updating this regulation will also better address one of NIDILRR’s core statutory purposes: To increase opportunities for researchers who are members of traditionally underserved populations, including researchers who are members of minority groups and researchers who are individuals with disabilities (29 U.S.C. 760(7)). (2) NIDILRR’s statute calls for a Rehabilitation Engineering Research Centers program (29 U.S.C. 764(b)(3)(A)), but related peer review criteria in 45 CFR 1330.24 do not currently emphasize the importance of engineering Research & Development methods.

Alternatives: None.

Anticipated Cost and Benefits: ACL anticipates little to no cost associated with this aspect of existing regulation. The benefits include the potential for greater representation of people with disabilities and other underrepresented populations among NIDILRR-sponsored researchers. The regulation update also will incite grantees of the NIDILRR Rehabilitation Engineering Research Centers program to include engineering Research & Development methods in their funded research projects.

Risks: NIDILRR is addressing significant risks that (1) The research it sponsors may not address the needs and experiences of the full diversity of people with disabilities, and (2) NIDILRR Rehabilitation Engineering Research Centers are not optimally emphasizing engineering R&D methods.

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Regulatory Flexibility Analysis Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Agency Contact: Richard Nicholls, Chief of Staff and Executive Secretary, Department of Health and Human Services, Administration for Community Living, 330 C Street SW, Room 1004B, Washington, DC 20201, Phone: 202 795–7415, Fax: 202 205–0390, Email: rich.nicholls@acl.hhs.gov. RIN: 0985–AA16

BILLING CODE 4150–03–P

DEPARTMENT OF HOMELAND SECURITY (DHS)

Fall 2021 Statement of Regulatory Priorities

The Department of Homeland Security (DHS or Department) was established in 2003 pursuant to the Homeland Security Act of 2002, Public Law 107–296. The DHS mission statement contains these words: “With honor and integrity, we will safeguard the American people, our homeland, and our values.”

DHS was created in the aftermath of the horrific attacks of 9/11, and its distinctive mission is defined by that commitment. The phrase “homeland security” refers to the security of the American people, the homeland (understood in the broadest sense), and the nation’s defining values. A central part of the mission of protecting “our values” includes fidelity to law and the rule of law, reflected above all in the Constitution of the United States, and also in statutes enacted by Congress, including the Administrative Procedure Act. That commitment is also associated...
with a commitment to individual dignity. Among other things, the attacks of 9/11 were attacks on that value as well.

The regulatory priorities of DHS are founded on insistence on the rule of law—and also on a belief that individual dignity, symbolized and made real by the opening words of the Constitution (“We the People”), the separation of powers, and the Bill of Rights (including the Due Process Clause), helps to define our mission. Fulfilling that mission requires the dedication of more than 240,000 employees in jobs that range from aviation and border security to emergency response, from cybersecurity analyst to chemical facility inspector, from the economist seeking to identify the consequences of our actions to the scientist and policy analyst seeking to make the nation more resilient against flooding, drought, extreme heat, and wildfires. Our duties are wide-ranging, but our goal is clear: Keep America safe.

Six homeland security missions make up DHS’s strategic plan: (1) Counter terrorism and homeland security threats; (2) secure U.S. borders and approaches; (3) secure cyberspace and critical infrastructure; (4) preserve and uphold the Nation’s prosperity and economic security; (5) strengthen preparedness and resilience (including resilience from risks actually or potentially associated with climate change); (4) to modernization of existing requirements; and (5) to reducing unjustified barriers and burdens, including administrative burdens.

DHS strives for organizational excellence and uses a centralized and unified approach to managing its regulatory resources. The Office of the General Counsel manages the Department’s regulatory program, including the agenda and regulatory plan. In addition, DHS senior leadership reviews each significant regulatory project in order to ensure that the project fosters and supports the Department’s mission.

The Department is committed to ensuring that all of its regulatory initiatives are aligned with its guiding principles to protect civil rights and civil liberties, integrate our actions, listen to those affected by our actions, build coalitions and partnerships, eliminate unjustified burdens and barriers, develop human resources, innovate, and be accountable to the American public.

DHS is strongly committed to the principles described in Executive Orders 13563 and 12866 (as amended). Both Executive Orders 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. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits of regulatory actions, harmonizing rules, and of promoting flexibility. Executive Order 13563 explicitly draws attention to human dignity and to equity.

Finally, the Department values public involvement in the development of its regulatory plan, agenda, and regulations. It is particularly concerned with the impact its regulations have on small businesses and startups, consistent with its commitment to promoting economic growth. Consistent with President Biden’s Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13965), DHS is also concerned to ensure that its regulations are equitable, and that they do not have unintended or adverse effects on (for example) women, disabled people, people of color, or the elderly. Its general effort to modernize regulations, and to remove unjustified barriers and burdens, is meant in part to avoid harmful effects on small businesses, startups, and disadvantaged groups of multiple sorts. DHS and its components continue to emphasize the use of plain language in our regulatory documents to promote a better understanding of regulations and to promote increased public participation in the Department’s regulations. We want our regulations to be transparent and “navigable,” so that people are aware of how to comply with them (and in a position to suggest improvements).

The Fall 2021 regulatory plan for DHS includes regulations from multiple DHS components, including U.S. Citizenship and Immigration Services (USCIS), the U.S. Coast Guard (the Coast Guard), U.S. Customs and Border Protection (CBP), Transportation Security Administration (TSA), the U.S. Immigration and Customs Enforcement (ICE), the Federal Emergency Management Agency (FEMA), and the Cybersecurity and Infrastructure Security Agency (CISA). We next describe the regulations that comprise the DHS fall 2021 regulatory plan.

Federal Emergency Management Agency

The Federal Emergency Management Agency (FEMA) is the government agency responsible for helping people before, during, and after disasters. FEMA supports the people and communities of our Nation by providing experience, perspective, and resources in emergency management. FEMA is particularly focused on national resilience in the face of the risks of flooding, drought, extreme heat, and wildfire; it is acutely aware that these risks, and others, are actually or potentially aggravated by climate change. FEMA seeks to ensure, to the extent possible, that changing weather
conditions do not mean a more vulnerable nation. FEMA is also focused on individual equity, and it is aware that administrative burdens and undue complexity might produce inequitable results in practice.

Consistent with President Biden’s Executive Order on Climate Related Financial Risk (E.O. 14030), FEMA will propose a regulation titled National Flood Insurance Program: Standard Flood Insurance Policy, Homeowner Flood Form. The National Flood Insurance Program (NFIP), established pursuant to the National Flood Insurance Act of 1968, is a voluntary program in which participating communities adopt and enforce a set of minimum floodplain management requirements to reduce future flood damages. This proposed rule would revise the Standard Flood Insurance Policy by adding a new Homeowner Flood Form and five accompanying endorsements. The new Homeowner Flood Form would replace the Dwelling Form as a source of coverage for one-to-four family residences. Together, the new Form and endorsements would more closely align with property and casually homeowners’ insurance and provide increased options and coverage in a more user-friendly and comprehensible format.

FEMA will also propose a regulation titled Individual Assistance Program Equity to further align with Executive Order 13895. Climate change results in more frequent and/or intense extreme weather events like severe storms, flooding, and wildfires, disproportionately impacting the most vulnerable in society. FEMA will propose to amend its Individual Assistance (IA) regulations to increase equity and ease of entry to the IA Program. To provide a full opportunity for underserved communities to participate, FEMA will propose to amend application of “safe, sanitary, and functional” for IA repair assistance; re-evaluate the requirement to apply for a Small Business Administration loan prior to receipt of Other Needs Assistance; add eligibility criteria for its Serious Needs & Displacement Assistance; amend its requirements for Continued Temporary Housing Assistance; re-evaluate its approach to insurance proceeds; and amend its appeals process. FEMA will also propose revisions to reflect changes to statutory authority that have not yet been implemented in regulation, to include provisions for utility and security deposit payments, lease and repair of multi-family rental housing, childcare assistance, and maximum assistance limits.

FEMA will issue a regulation titled Amendment to the Public Assistance Program’s Simplified Procedures Large Project Threshold. It will revise its regulations governing the Public Assistance program to update the monetary threshold at or below which FEMA will obligate funding based on an estimate of project costs, and above which FEMA will obligate funding based on actual project costs. This rule will ensure FEMA and recipients can more efficiently process unobligated Project Worksheets for COVID-19 declarations, which continue to fund important pandemic-related work, while avoiding unnecessary confusion and administrative burden by not affecting previous project size determinations.

On October 12, 2021, FEMA issued a Request for Information to receive the public’s input on revising the NFIP’s floodplain management standards for land management and use regulations to better align with the current understanding of flood risk and flood risk reduction approaches, as directed by Executive Order 14030. FEMA seeks input on the floodplain management standards that communities should adopt to result in safer, stronger, and more resilient communities. Additionally, FEMA seeks input on how the NFIP can better promote protection of and minimize any adverse impact to threatened and endangered species, and their habitats.

United States Citizenship and Immigration Services

U.S. Citizenship and Immigration Services (USCIS) is the government agency that administers the nation’s lawful immigration system, safeguarding its integrity and promise by efficiently and fairly adjudicating requests for immigration benefits while protecting Americans, securing the homeland, and honoring our values. USCIS is committed to taking the necessary steps to reduce barriers to legal immigration, increase access to immigration benefits (consistent with law), and reinvigorate the size and scope of humanitarian relief. In the coming year, USCIS intends to pursue several regulatory actions that support these goals while balancing our fiscal stability.

Asylum Reforms. This Administration is focused on pursuing regulations to rebuild and streamline the asylum system, consistent with President Biden’s Executive Order on Creating a Comprehensive Regional Framework to Address the Causes of Migration, to Mitigate Migration Throughout North and Central America, and to Provide Safe and Orderly Processing of Asylum Seekers at the United States Border (E.O. 14010). On August 20, 2021, DHS/USCIS and DOJ/Executive Office of Immigration Review (EOIR) jointly proposed regulatory amendments that aim to accelerate the adjudication process for individuals in expedited removal proceedings who are seeking asylum, withholding of removal, or protection under the Convention Against Torture. The current system in place has resulted in unsustainable backlogs that span many years. USCIS and EOIR will seek to issue a final rule that makes concrete and lasting improvements in the processing of those cases after considering public input received on the proposed rule.

(Procedures for Credible Fear Screening and Consideration of Asylum, Withholding of Removal, and CAT Protection Claims by Asylum Officers). In addition, USCIS will propose regulations to remove barriers to affirmative asylum claims, while also proposing processing timeframes for initial application for employment authorization applications filed by pending asylum applicants that reflect the operational capabilities of USCIS.

(Rescission of “Asylum Application, Interview, & Employment Authorization” Rule and Change to “Removal of 30-Day Processing Provision for Asylum Applicant Related Form I-765 Employment Authorization”). USCIS and EOIR will also take steps to remove or modify regulatory provisions that have created unnecessary hurdles in the asylum system, many of which are currently enjoined by various courts. (Bars to Asylum Eligibility and Procedures; Procedures for Asylum and Withholding of Removal; Credible Fear and Reasonable Fear Review). Finally, USCIS and EOIR will jointly propose updates to their regulations to clarify eligibility for asylum and withholding, and better describe the circumstances in which a person should be considered a member of a “particular social group.” (Asylum and Withholding Definitions).

Review of the Public Charge of Inadmissibility Ground. On August 23, 2021, USCIS published an Advance Notice of Proposed Rulemaking (ANPRM) to gather input from interested and impacted stakeholders on how USCIS should implement the public charge ground of inadmissibility. This action was the first step taken in response to President Biden’s Executive Order on Restoring Faith in Our Legal Immigration Systems and Strengthening Integration and Inclusion Efforts for New Americans (E.O. 14012). USCIS will propose regulations to define the
Coast Guard (USCG) partnerships with maritime stakeholders. Consistent standards of universal application and enforcement, which encourage safe, efficient, and responsible maritime commerce, are vital to the success of the maritime industry. The Coast Guard’s ability to field versatile capabilities and highly trained personnel is one of the U.S. Government’s most significant and important strengths in the maritime environment.

America is a maritime nation, and our security, resilience, and economic prosperity are intrinsically linked to the oceans. Safety, efficient waterways, and freedom of transit on the high seas are essential to our well-being. The Coast Guard is leaning forward, poised to meet the demands of the modern maritime environment. The Coast Guard creates value for the public through solid prevention and response efforts. Activities involving oversight and regulation, enforcement, maritime presence, and public and private partnership foster increased maritime safety, security, and stewardship.

The statutory responsibilities of the Coast Guard include ensuring marine safety and security, preserving maritime mobility, protecting the marine environment, enforcing U.S. laws and international treaties, and performing search and rescue. The Coast Guard supports the Department’s overarching goals of mobilizing and organizing our Nation to secure the homeland from terrorist attacks, natural disasters, and other emergencies. These goals include protection against the risks associated with climate change, and the Coast Guard seeks to obtain scientific information to assist in that task, while also acting to promote resilience and adaptation.

The Coast Guard highlights the following regulatory actions:

- **Shipping Safety Fairways Along the Atlantic Coast.** The Coast Guard published an ANPRM on June 19, 2020. The Coast Guard is reviewing comments to help develop a proposed rule that would establish shipping safety fairways (fairways) along the Atlantic Coast of the United States. Fairways are marked routes for vessel traffic. They facilitate the direct and unobstructed transit of ships. The proposed fairways will be based on studies about vessel traffic along the Atlantic Coast. The Coast Guard is taking this action to ensure that obstruction-free routes are preserved to and from U.S. ports and along the Atlantic coast and to reduce the risk of collisions, allisions and grounding, as well as alleviate the chance of increased time and expenses in transit.

**Electronic Chart and Navigation Equipment Carriage Requirements.** The Coast Guard will seek comment on the modification of its chart and navigational equipment regulations. We plan to publish an ANPRM that outlines the Coast Guard’s strategy to revise the chart and navigational equipment requirements for all commercial U.S.-flagged vessels and foreign-flagged vessels operating in the waters of the United States to fulfill the electronic chart use requirements as required by statute. Acceptable standards and capabilities need to be clarified before paper charts are discontinued and replaced by digital electronic navigation charts. The ANPRM should provide us with information on how widely electronic charts are used, who is using them, the appropriate equipment requirements for different vessel classes, and where they operate. The public comments should better enable us to tailor proposed electronic charts requirements to vessel class and location.

**MARPOL Annex VI; Prevention of Air Pollution from Ships.** The Coast Guard is proposing regulations to carry out the provisions of Annex VI of the MARPOL Protocol, which is focused on the prevention of air pollution from ships. The Act to Prevent Pollution from Ships has already given direct effect to most provisions of Annex VI, and the Coast Guard and the Environmental Protection Agency have carried out some Annex VI provisions through previous rulemakings. This proposed rulemaking would fill gaps in the existing framework for carrying out the provisions of Annex VI. Chapter 4 of Annex VI contains shipboard energy efficiency measures that include short-term measures reducing carbon emissions linked to climate change and supports Administration goals outlined in Executive Order 14008 titled Tackling the Climate Crisis at Home and Abroad. This proposed rulemaking would apply to U.S.-flagged ships. It would also apply to foreign-flagged ships operating either in U.S. navigable waters or in the U.S. Exclusive Economic Zone.

**United States Customs and Border Protection**

Customs and Border Protection (CBP) is the Federal agency principally responsible for the security of our Nation’s borders, both at and between the ports of entry into the United States. CBP must accomplish its border security and enforcement mission without stifling the flow of legitimate trade and travel. The primary mission of CBP is its homeland security mission, that is, to...
prevent terrorists and terrorist weapons from entering the United States. An important aspect of this mission involves improving security at our borders and ports of entry, but it also means extending our zone of security beyond our physical borders.

CBP is also responsible for administering laws concerning the importation of goods into the United States and enforcing the laws concerning the entry of persons into the United States. This includes regulating and facilitating international trade; collecting import duties; enforcing U.S. trade, immigration and other laws of the United States at our borders; inspecting imports; overseeing the activities of persons and businesses engaged in importing; enforcing the laws concerning smuggling and trafficking in contraband; apprehending individuals attempting to enter the United States illegally; protecting our agriculture and economic interests from harmful pests and diseases; servicing all people, vehicles, and cargo entering the United States; requiring export controls; and protecting U.S. businesses from theft of their intellectual property.

In carrying out its mission, CBP’s goal is to facilitate the processing of legitimate trade and people efficiently without compromising security. Consistent with its primary mission of homeland security, CBP intends to issue several regulations that are intended to improve security at our borders and ports of entry. During the upcoming year, CBP will also work on various projects to enhance CBP processing, reduce duplicative processes, reduce various burdens on the public, and automate various paper forms. Below, CBP provides highlights of certain planned actions for the coming fiscal year.

**Implementation of the Electronic System for Travel Authorization (ESTA) at U.S. Land Borders—Automation of CBP Form I–94W.** CBP intends to amend existing regulations to implement the ESTA requirements under the Implementing Recommendations of the 9/11 Commission Act of 2007 for noncitizens who intend to enter the United States under the Visa Waiver Program (VWP) at land ports of entry. Currently, noncitizens from VWP countries must provide certain biographic information to U.S. CBP officers at land ports of entry on a paper form. Under this rule, these VWP travelers would instead provide this information to CBP electronically through ESTA prior to application for admission to the United States. In addition to fulfilling a statutory mandate, this rule will strengthen national security through enhanced traveler vetting, will streamline the processing of visitors, will reduce inadmissible traveler arrivals, and will save time for both travelers and the government. (Note: There is no associated Regulatory Plan entry for this rule because this rule is non-significant under Executive Order 12866. There is an entry, however, in the Unified Agenda.)

**Automation of CBP Form I–418 for Vessels.** CBP intends to amend existing regulations regarding the submission of Form I–418, Passenger List—Crew List. Currently, the master or agent of every commercial vessel arriving in the United States, with limited exceptions, must submit a paper Form I–418 to CBP at the port where immigration inspection is performed. Most commercial vessel operators are also required to submit a paper Form I–418 to CBP at the final U.S. port prior to departing for a foreign port. Under this rule, most vessel operators would be required to electronically submit the data elements on Form I–418 to CBP through the National Vessel Movement Center in lieu of submitting a paper form. This rule would eliminate the need to file the paper Form I–418 in most cases. This rule is included in this narrative because it reduces administrative and paperwork burdens on the regulated public. (Note: There is no associated Regulatory Plan entry for this rule because this rule is non-significant under Executive Order 12866. There is an entry, however, in the Unified Agenda.)

**Advance Passenger Information System: Electronic Validation of Travel Documents.** CBP intends to amend current Advance Passenger Information System (APIS) regulations to incorporate additional carrier requirements that would further enable CBP to determine whether each passenger is traveling with valid, authentic travel documents prior to the passenger boarding the aircraft. The proposed regulation would require commercial air carriers to receive a second message from CBP that would state whether CBP matched the travel documents of each passenger to a valid, authentic travel document recorded in CBP’s databases. The proposed regulation would also require air carriers to transmit additional data elements regarding contact information through APIS for all commercial aircraft passengers arriving in the United States to support border operations and national security. CBP expects that the collection of these elements would enable CBP to further support the Center for Disease Control and Prevention’s (CDC’s) mission in monitoring and tracing the contacts for persons involved in health incidents (e.g., COVID–19). This action will result in time savings to passengers and cost savings to CBP, carriers, and the public.

In addition to the regulations that CBP issues to promote DHS’s mission, CBP issues regulations related to the mission of the Department of the Treasury.

Under section 403(1) of the Homeland Security Act of 2002, the former-U.S. Customs Service, including functions of the Secretary of the Treasury relating thereto, transferred to the Secretary of Homeland Security. As part of the initial organization of DHS, the Customs Service inspection and trade functions were combined with the immigration and agricultural inspection functions and the Border Patrol and transferred into CBP. The Department of the Treasury retained certain regulatory authority of the U.S. Customs Service relating to customs revenue function. In the coming year, CBP expects to continue to issue regulatory documents that will facilitate legitimate trade and implement trade benefit programs. For a discussion of CBP regulations regarding the customs revenue function, see the regulatory plan of the Department of the Treasury.

**Transportation Security Administration**

The Transportation Security Administration (TSA) protects the Nation’s transportation systems to ensure freedom of movement for people and commerce. TSA applies an intelligence-driven, risk-based approach to all aspects of its mission. This approach results in layers of security to mitigate risks effectively and efficiently. TSA seeks to ensure ever-improving “customer service” so as to improve the experience of the many millions of travelers whom it serves. In fiscal year 2022, TSA is prioritizing the following actions that are required to meet statutory mandates and that are necessary for national security.

**Vetting of Certain Surface Transportation Employees.** TSA will propose a rule that requires security threat assessments for security coordinators and other frontline employees of certain public transportation agencies (including rail mass transit and bus systems), railroads (freight and passenger), and over-the-road bus owner/operators. The NPRM will also propose provisions to implement TSA’s statutory requirement to recover its cost of vetting user fees. While many stakeholders conduct background checks on their employees, their actions are limited based upon the data they can access. Through this rule,
TSA will be able to conduct a more thorough check against terrorist watch-lists of individuals in security-sensitive positions.

**Flight Training Security.** In 2004, TSA published an Interim Final Rule (IFR) that requires flight schools to notify TSA when noncitizens, and other individuals designated by TSA, apply for flight training or recurrent training. TSA subsequently issued exemptions and interpretations in response to comments on the IFR, questions raised during operation of the program since 2004, and a notice extending the comment period on May 18, 2018. Based on the comments and questions received, TSA is finalizing the rule with modifications. TSA is considering modifications that would change the frequency of security threat assessments from a high-frequency event-based interval to a time-based interval, clarify the definitions and other provisions of the rule, and enable industry to use TSA-provided electronic recordkeeping systems for all documents required to demonstrate compliance with the rule.

**Indirect Air Carrier Security.** Current regulations for Indirect Air Carriers (IACs) require annual renewal of the IAC’s security program and prompt notification to TSA of any changes to operations related to information previously provided to TSA. This rule will propose a three-year renewal schedule, rather than annual renewal. This change will align the security program renewal requirement with those applicable to other regulated entities within the air cargo industry. These changes will not have a negative impact on security as TSA will maintain the requirement to notify the agency of changes to operations and will continue its robust inspection and compliance program. TSA believes this action will reduce burdens on an industry affected by the COVID-19 public health crisis and enhance the industry’s ability to focus limited human resources on the core tasks of moving air cargo.

**Cybersecurity Requirements for Certain Surface Owner/Operators.** On July 28, 2021, the President issued the National Security Memorandum on Improving Cybersecurity for Critical Infrastructure Control Systems. Consistent with that Memorandum and in response to the ongoing cybersecurity threat to pipeline systems, TSA issued security directives to owners and operators of TSA-designated critical pipelines that transport hazardous liquids and natural gas. The security directives implement urgently needed protections against cyber intrusions. The first directive, issued in May 2021, requires critical owner/operators to (1) report confirmed and potential cybersecurity incidents to DHS’s Cybersecurity and Infrastructure Security Agency (CISA); (2) designate a Cybersecurity Coordinator to be available 24 hours a day, seven days a week; (3) review current cybersecurity practices; and (4) identify any gaps and related remediation measures to address cyber-related risks and report the results to TSA and CISA within 30 days of issuance of the security directive. A second security directive, issued in July 2021, requires these owners and operators to (1) implement specific mitigation measures to protect against ransomware attacks and other known threats to information technology and operational technology systems; (2) develop and implement a cybersecurity contingency and recovery plan; and (3) conduct a cybersecurity architecture design review. TSA is committed to enhancing and sustaining cybersecurity in transportation and intends to issue a rulemaking to codify these and other requirements for certain surface transportation owner-operators.

**Amending Vetting Requirements for Employees with Access to a Security Identification Display Area.** The FAA Extension, Safety, and Security Act of 2016 mandates that TSA consider modifications to the list of disqualifying criminal offenses and criteria, develop a waiver process for approving the issuance of credentials for unescorted access, and propose an extension of the look back period for disqualifying crimes. Based on these requirements, and current intelligence pertaining to the “insider threat,” TSA is developing a proposed rule. The rule would revise current vetting requirements to enhance eligibility and disqualifying criminal offenses for individuals seeking or having unescorted access to any Security Identification Display Area of an airport.

**United States Immigration and Customs Enforcement**

U.S. Immigration and Customs Enforcement (ICE) is the principal criminal investigative arm of DHS and one of the three Department components charged with the criminal and civil enforcement of the Nation’s immigration laws. Its primary mission is to protect national security, public safety, and the integrity of our borders through the criminal and civil enforcement of Federal law governing border control, customs, trade, and immigration. During the coming fiscal year, ICE will focus rulemaking efforts on regulations pertaining to adjusting fees, including the rule mentioned below.

**Fee Adjustment for U.S. Immigration and Customs Enforcement Form I–246, Application for a Stay of Deportation or Removal.** ICE will propose a rule that would adjust the fee for adjudicating and handling Form I–246, Application for a Stay of Deportation or Removal. The Form I–246 fee was last adjusted in 1989. After a comprehensive fee review, ICE has determined that the current Form I–246 fee does not recover the full costs of processing and adjudicating Form I–246. The rule will also clarify the availability of Form I–246 fee waivers.

**Cybersecurity and Infrastructure Security Agency**

The Cybersecurity and Infrastructure Security Agency (CISA) is responsible for leading the national effort to develop cybersecurity and critical infrastructure security programs, operations, and associated policy to enhance the security and resilience of physical and cyber infrastructure.

**Ammonium Nitrate Security Program.** This rule implements a 2007 amendment to the Homeland Security Act. The amendment requires DHS to “regulate the sale and transfer of ammonium nitrate facility . . . to prevent the misappropriation or use of ammonium nitrate in an act of terrorism.” CISA published a Notice of Proposed Rulemaking in 2011. CISA is planning to issue a Supplemental Notice of Proposed Rulemaking. A more detailed description of the priority regulations that comprise the DHS regulatory plan follows.

**DHS—U.S. CITIZENSHIP AND IMMIGRATION SERVICES (USCIS)**

**Proposed Rule Stage**

**76. Procedures for Asylum and Withholding of Removal; Credible Fear and Reasonable Fear Review**

**Priority:** Other Significant.

**Legal Authority:** 8 U.S.C. 1158; 8 U.S.C. 1225; 8 U.S.C. 1231 and 1231 (note)

**CFR Citation:** 8 CFR 235; 8 CFR 208; 8 CFR 1208.

**Legal Deadline:** None.

**Abstract:** On December 11, 2020, the Department of Justice and the Department of Homeland Security (collectively, “the Departments”) published a final rule titled Procedures for Asylum and Withholding of Removal; Credible Fear and Reasonable Fear Review (RINs 1225–AA94 and 1615–AC42) to amend the regulations governing credible fear determinations so that individuals found to have such
a fear will have their claims for asylum, withholding of removal under section 241(b)(3) of the Immigration and Nationality Act ("INA" or "the Act") ("statutory withholding of removal"), or protection under the regulations issued pursuant to the legislation implementing the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment ("CAT"), adjudicated by an immigration judge within the Executive Office for Immigration Review ("EOIR") in separate proceedings (rather than in proceedings under section 240 of the Act), and to specify what standard of review applies in such proceedings. The final rule amended the regulations regarding asylum, statutory withholding of removal, and withholding and deferral of removal under the CAT regulations. The final rule also made changes to the standards for adjudication of applications for asylum and statutory withholding. The Departments are planning to rescind or modify the December 2020 rule, in several rulemaking efforts. The Departments have proposed to rescind certain portions of the final rule (including regulations related to credible fear screenings) as part of the rulemaking action described in RIN 1615–AC67. The Departments will also propose to rescind or modify the remaining portions of the December 2020 rule under this RIN, 1615–AC42. Statement of Need: The Departments are reviewing the regulatory changes made in the final rule in light of the issuance of Executive Order 14010 and Executive Order 14012. This rule is needed to ensure that the regulations align with the goals and principles outlined in Executive Order 14010 and Executive Order 14012. Anticipated Cost and Benefits: DHS is currently considering the specific cost and benefit impacts associated with the proposal to rescind or modify the December 2020 rule.

DHS—USCIS

77. Deferred Action for Childhood Arrivals

| CFR Citation: 8 CFR 106; 8 CFR 236; 8 CFR 274a. |
| Legal Deadline: None. |
| Abstract: On June 15, 2012, the DHS established the DACA policy. The policy directed USCIS to create a process to defer removal of certain noncitizens who years earlier came to the United States as children, meet other criteria, and do not present other circumstances that would warrant removal. On January 20, 2021, President Biden directed DHS, to take all appropriate actions to preserve and fortify DACA, consistent with applicable law. On July 16, 2021, the U.S. District Court for the Southern District of Texas vacated the June 2012 Memorandum that created the DACA policy and permanently enjoined DHS from “administering the DACA program and from reimplementing DACA without compliance with the APA.” However, the district court temporarily stayed its vacatur and injunction with respect to most individuals granted deferred action under DACA on or before July 16, 2021, including with respect to their renewal requests. The district court’s vacatur and injunction were based, in part, on its conclusion that the June 2012 Memorandum announced a legislative rule that required notice-and-comment rulemaking. The district court further remanded the DACA policy to DHS for further consideration. DHS has announced its intent to appeal the district court’s decision. Consistent with the Presidential Memorandum, DHS intends to engage in notice- and-comment rulemaking to consider all issues raised by the court, including those identified by the district court relating to the policy’s substantive legality. |

DHS—USCIS

78. Asylum and Withholding Definitions

| Unfunded Mandates: Undetermined. |
| CFR Citation: 8 CFR 2; 8 CFR 208; 8 CFR 1208. |
| Legal Deadline: None. |
| Abstract: This rule proposes to amend Department of Homeland Security (DHS) and Department of Justice (DOJ) regulations that govern eligibility for asylum and withholding of removal. The amendments focus on portions of the regulations that deal with the definitions of membership in a particular social group, the requirements for failure of State
protection, and determinations about whether persecution is on account of a protected ground. This rule is consistent with Executive Order 14010 of February 2, 2021, which directs the Departments to, within 270 days, promulgate joint regulations, consistent with applicable law, addressing the circumstances in which a person should be considered a member of a particular social group.

Statement of Need: This rule provides guidance on a number of key interpretive issues of the refugee definition used by adjudicators deciding asylum and withholding of removal (withholding) claims. The interpretive issues include whether persecution is inflicted on account of a protected ground, the requirements for establishing the failure of State protection, and the parameters for defining membership in a particular social group. This rule will aid in the adjudication of claims made by applicants whose claims fall outside of the rubric of the protected grounds of race, religion, nationality, or political opinion. One example of such claims which often fall within the particular social group concerns people who have suffered or fear domestic violence. This rule is expected to consolidate issues raised in a proposed rule in 2000 and to address issues that have developed since the publication of the proposed rule. This rule should provide greater stability and clarity in this important area of the law. This rule will also provide guidance to the following adjudicators: USCIS asylum officers, Department of Justice Executive Office for Immigration Review (EOIR) immigration judges, and members of the EOIR Board of Immigration Appeals (BIA).

Furthermore, on February 2, 2021, President Biden issued Executive Order 14010 that directs DOJ and DHS within 270 days of the date of this order, to promulgate joint regulations, consistent with applicable law, addressing the circumstances in which a person should be considered a member of a “particular social group,” as that term is used in 8 U.S.C. 1101(a)(42)(A), as derived from the 1951 Convention relating to the Status of Refugees and its 1967 Protocol.

Summary of Legal Basis: The purpose of this rule is to provide guidance on certain issues that have arisen in the context of asylum and withholding adjudications. The 1951 Geneva Convention relating to the Status of Refugees contains the internationally accepted definition of a refugee. United States immigration law incorporates an almost identical definition of a refugee as a person outside his or her country of origin “who is unable or unwilling to return to, and is unable or unwilling to avail himself or herself of the protection of, that country because of persecution or a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.” Section 101(a)(42) of the Immigration and Nationality Act.

DHS—USCIS


Unfunded Mandates: Undetermined.


CFR Citation: 8 CFR 208.3; 8 CFR 208.4; 8 CFR 208.7; 8 CFR 208.10; 8 CFR 274a.12; 8 CFR 274a.13; 8 CFR 274a.14.

Legal Deadline: None.

Abstract: DHS plans to issue a notice of proposed rulemaking that would rescind or substantively revise two final rules related to employment authorization for asylum applicants. On August 25, 2020, the Department of Homeland Security (DHS) published a final rule that modified DHS’s regulations governing asylum applications, interviews, and eligibility for employment authorization based on a pending asylum application. (85 FR 38532). On August 21, 2020, the Department of Homeland Security (DHS) published a final rule that removed a Department of Homeland Security (DHS) regulatory provision stating that U.S. Citizenship and Immigration Services (USCIS) has 30 days from the date an asylum applicant files the initial Form I–765, Application for Employment Authorization, to grant or deny that initial employment authorization application. (85 FR 37502).

Statement of Need: The proposed change is intended to help ensure the eligibility requirements for employment authorization for asylum applicants and processing times established in the DHS regulations are reasonable.

DHS—USCIS
80. U.S. Citizenship and Immigration Services Fee Schedule


Legal Authority: 8 U.S.C. 1356(m), (n) CFR Citation: 8 CFR 103; 8 CFR 106.

Legal Deadline: None.

Abstract: DHS will propose to adjust the fees charged by U.S. Citizenship and Immigration Services (USCIS) for
DHS—USCIS  
81. Bars to Asylum Eligibility and Procedures  

CFR Citation: 8 CFR 208; 8 CFR 235; 8 CFR 1003; 8 CFR 1208; 8 CFR 1235.  
Legal Deadline: None.  
Abstract: In 2020, the Department of Homeland Security and Department of Justice (collectively, the Departments) published final rules amending their respective regulations governing bars to asylum eligibility and procedures, including the Procedures for Asylum and Bars to Asylum Eligibility, (RINs 1125–AA87 and 1615–AC41), 85 FR 67202 (Oct. 21, 2020). Asylum Eligibility and Procedural Modifications, (RINs 1125–AA91 and 1615–AC44), 85 FR 82260 (Dec. 17, 2020) and Security Bars and Processing, (RINs 1125–AB08 and 1615–AC57), 85 FR 84160, (Dec. 23, 2020) final rules. The Departments propose to modify or rescind the regulatory changes promulgated in these three final rules consistent with Executive Order 14010 (Feb. 2, 2021).  
Statement of Need: The Departments are reviewing these regulations in light of the issuance of Executive Order 14010 and Executive Order 14012. This rule is needed to restore and strengthen the asylum system and to address inconsistencies with the goals and principles outlined in the Executive Order 14010 and Executive Order 14012.  
Anticipated Cost and Benefits: DHS is currently considering the specific cost and benefit impacts of the proposed provisions.  
Timetable:  

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Regulatory Flexibility Analysis Required: Yes.  
Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations.  
Government Levels Affected: None.  
RIN: 1615–AC68  

DHS—USCIS  
82. Inadmissibility on Public Charge Grounds  

Priority: Other Significant.  
CFR Citation: 8 CFR 212; 8 CFR 245; . . .  
Legal Deadline: None.  
Abstract: Section 4 of Executive Order 14012 of February 2, 2021 (86 FR 8277) directed DHS and other federal agencies to immediately review agency actions related to the public charge grounds of inadmissibility and deportability for noncitizens at sections 212(a)(4) and 237(a)(5) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(a)(4), 1227(a)(5)). DHS intends to proceed with rulemaking to define the term public charge and identify considerations relevant to the public charge inadmissibility determination. DHS will conduct the rulemaking consistent with section 212(a)(4) of the INA and consistent with the principles described in Executive Order 14012. Such principles include recognizing our character as a Nation of opportunity and of welcome and of providing due consideration to the confusion, fear, and negative public health consequences that may result from public charge policies.  
Consistent with section 6 of Executive Order 12866 (58 FR 51735) and section 2 of Executive Order 13563 (76 FR 3821), and in consideration of the significant public interest in this rulemaking proceeding, DHS published an advance notice of proposed rulemaking and notice of virtual public listening sessions on August 23, 2021. There is a 60-day public comment period and the listening sessions are scheduled for September 14 and October 5, 2021.  
Statement of Need: DHS published an advance notice of proposed rulemaking seeking broad public feedback on the public charge ground of inadmissibility to inform DHS’s development of a future regulatory proposal. DHS intends to use this feedback to develop a proposed rule that will be fully consistent with law; that will reflect empirical evidence to the extent relevant and available; that will be clear, fair, and comprehensible for officers as well as for noncitizens.
and their families; that will lead to fair and consistent adjudications and thus avoid unequal treatment of the similarly situated; and that will not otherwise unduly impose barriers on noncitizens seeking admission to or adjustment of status in the United States. DHS also intends to ensure that its regulatory proposal does not cause undue fear among immigrant communities or present other obstacles to immigrants and their families accessing public services available to them, particularly in light of the COVID–19 pandemic and the resulting long-term public health and economic impacts in the United States.

Anticipated Cost and Benefits: DHS is currently considering the specific cost and benefit impacts of the proposed provisions.

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Regulatory Flexibility Analysis
Required: Undetermined.  
Government Levels Affected: Undetermined.

URL For Public Comments: http://www.regulations.gov.


RIN: 1615–AC74

DHS—USCIS

Final Rule Stage

83. Procedures for Credible Fear Screening and Consideration of Asylum, Withholding of Removal and CAT Protection Claims by Asylum Officers


CFR Citation: 8 CFR 208; 8 CFR 235; 8 CFR 1003; 8 CFR 1208; 8 CFR 1235.  
Legal Deadline: None.

Abstract: On August 20, 2021 the Department of Justice (DOJ) and the Department of Homeland Security (DHS) (collectively, the Departments) published a Notice of Proposed Rulemaking (NPRM) to amend the regulations governing the determination of certain protection claims raised by individuals subject to expedited removal and found to have a credible fear of persecution or torture. Under the proposed rule, such individuals would have their claims for asylum, withholding of removal under section 241(b)(3) of the Immigration and Nationality Act (INA or the Act) (statutory withholding of removal), or protection under the regulations issued pursuant to the legislation implementing U.S. obligations under Article 3 of the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT) initially adjudicated by an asylum officer within U.S. Citizenship and Immigration Services (USCIS). Such individuals who are denied protection would be able to seek prompt, de novo review with an immigration judge (IJ) in the DOJ Executive Office for Immigration Review (EOIR), with appeal available to the Board of Immigration Appeals (BIA). These changes are intended to improve the Departments’ ability to consider the asylum claims of individuals encountered at or near the border more promptly while ensuring fundamental fairness.

In conjunction with the above changes, the Departments are proposing to return the regulatory framework governing the credible fear screening process so as to once more apply the longstanding “significant possibility” screening standard to all protection claims, but not apply the mandatory bars to asylum and withholding of removal (with limited exception) at this initial screening stage. The Departments also propose that, if an asylum officer makes a positive credible fear determination, the documentation the USCIS asylum officer creates from the individual’s sworn testimony during the credible fear screening process would serve as an initial asylum application, thereby improving efficiency in the asylum adjudication system. Lastly, the Departments are proposing to allow, when detention is unavailable or impracticable, for the consideration of parole prior to a positive credible fear determination of an individual placed into expedited removal who makes a fear claim. The Departments are reviewing the public comments received and plan to issue a final rule.

Statement of Need: There is wide agreement that the system for dealing with asylum and related protection claims at the southwest border has long been overwhelmed and in desperate need of repair. As the number of such claims has skyrocketed over the years, the system has proven unable to keep pace, resulting in large backlogs and lengthy adjudication delays. A system that takes years to reach a result delays justice and certainty for those who need protection, and it encourages abuse by those who will not qualify for protection and smugglers who exploit the delay for profit. The aim of this rule is to begin replacing the current system, within the confines of the law, with a better and more efficient one that will adjudicate protection claims fairly and expeditiously.

Anticipated Cost and Benefits: DHS estimated the resource cost needed to implement and operationalize the rule along a range of possible future credible fear volumes. The average annualized costs could range from $179.5 million to $995.8 million at a 7 percent discount rate. At a 7 percent discount factor, the total ten-year costs could range from $1.3 billion to $7.0 billion, with a midrange of $3.2 billion.

There could also be cost-savings related to Forms I–589 and I–765 filing volume changes. In addition, some asylum applicants may realize potential early labor earnings, which could constitute a transfer from workers in the U.S. labor force to certain asylum applicants, as well as tax impacts.

Qualitative benefits include, but may not be limited to: (i) Beneficiaries of new parole standards may not have to wait lengthy times for a decision on whether their asylum claims will receive further consideration; (ii) some individuals could benefit from de novo review by an IJ of the asylum officer’s denial of their asylum; (iii) DOJ–EOIR may focus efforts on other priority work and reduce its substantial current backlog; (iv) as some applicants may be able to earn income earlier than they otherwise could currently, burdens to the support network of the applicant may be lessened.

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Regulatory Flexibility Analysis
Required: No.

Government Levels Affected: None.

International Impacts: This regulatory action will be likely to have
international trade and investment effects, or otherwise be of international interest.

URL For Public Comments: http://www.regulations.gov.


Related RIN: Related to 1125–AB20.
RIN: 1615–AC67

DHS—U.S. COAST GUARD (USCG)

Prerule Stage

84. Electronic Chart and Navigation Equipment Carriage Requirements

Priority: Other Significant.
Legal Authority: 46 U.S.C. 3105

Legal Deadline: None.

Abstract: The Coast Guard seeks comments regarding the modification of the chart and navigational equipment requirements in titles 33 and 46 of the Code of Federal Regulations. This advance notice of proposed rulemaking (ANPRM) outlines the Coast Guard’s broad strategy to revise the chart and navigational equipment requirements for all commercial U.S.-flagged vessels and foreign-flagged vessels operating in the waters of the United States to fulfill the electronic chart use requirements as required by statute. This ANPRM is necessary to obtain additional information from the public before drafting a proposed rule that better tailors electronic charts requirements to vessel class and location.

Statement of Need: In this ANPRM, we are seeking information on how widely electronic charts are used, which types of vessels are using them, and where the vessels operate, as well as views on the appropriate equipment requirements for different vessel classes. Issuing this ANPRM to obtain information from the public before drafting a proposed rule should enable us to issue a proposed rule that better tailors electronic charts requirements to vessel class and location.

Alternatives: The Coast Guard will use the information solicited from the ANPRM to shape regulatory language and alternatives.

Anticipated Cost and Benefits: The Coast Guard will use the ANPRM to solicit public input to help develop estimates of the costs and benefits of any proposed regulation.

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Regulatory Flexibility Analysis Required: Undetermined.
Government Levels Affected: Undetermined.
Federalism: Undetermined.
Additional Information: Docket number USCG–2021–0291.

Agency Contact: John Stone, Program Manager, Department of Homeland Security, U.S. Coast Guard, Office of Navigation Systems (CG–NAV), 2703 Martin Luther King Jr. Avenue SE, STOP 7418, Washington, DC 20593–7418, Phone: 202 372–1093, Email: john.m.stone2@uscg.mil.
RIN: 1625–AC74

DHS—USCG

Proposed Rule Stage

85. Shipping Safety Fairways Along the Atlantic Coast

Priority: Other Significant.
Legal Authority: 46 U.S.C. 70003
CFR Citation: 33 CFR 166.
Legal Deadline: None.

Abstract: The Coast Guard seeks comments regarding the possible establishment of shipping safety fairways (fairways) along the Atlantic Coast of the United States. Fairways are marked routes for vessel traffic in which any obstructions are prohibited. The proposed fairways are based on two studies about vessel traffic along the Atlantic Coast. The Coast Guard is coordinating this action with the Bureau of Offshore Energy Management (BOEM) to minimize the impact on potential offshore energy leases.

Statement of Need: This rulemaking would establish shipping safety fairways along the Atlantic coast of the United States to facilitate the direct and unobstructed transits of ships. The establishment of fairways would ensure that obstruction-free routes are preserved to and from U.S. ports and along the Atlantic Coast. This will reduce the risk of collision, allision and grounding, as well as alleviate the chance of increased time and expenses in transit.

Summary of Legal Basis: Section 70003 of title 46 United States Code (46 U.S.C. 70003) directs the Secretary of the department in which the Coast Guard resides to designate necessary fairways that provide safe access routes for vessels proceeding to and from U.S. ports.

Alternatives: The ANPRM outlined the Coast Guard’s plans for fairways along the Atlantic Coast and requested information and data associated with the regulatory concepts. The Coast Guard will use this information and data to shape regulatory language and alternatives and assess the associated impacts in the NPRM.

Anticipated Cost and Benefits: The fairways are intended to preserve traditional vessel navigation routes and are not mandatory. The Coast Guard anticipates the proposed fairways to improve navigational safety.

Risks: The Bureau of Ocean Energy Management (BOEM) is leasing offshore areas that could affect customary shipping routes. Expedient pursuit of this rulemaking is intended to prevent conflict between customary shipping routes and areas that may be leased by BOEM.

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Regulatory Flexibility Analysis Required: Undetermined.
Government Levels Affected: Undetermined.
Federalism: Undetermined.

URL For Public Comments: www.regulations.gov.

Agency Contact: John Stone, Program Manager, Department of Homeland Security, U.S. Coast Guard, Office of Navigation Systems (CG–NAV), 2703 Martin Luther King Jr. Avenue SE, STOP 7418, Washington, DC 20593–7418, Phone: 202 372–1093, Email: john.m.stone2@uscg.mil.
RIN: 1625–AC57
86. Marpol Annex VI; Prevention of Air Pollution From Ships

Priority: Other Significant.
Legal Authority: 33 U.S.C. 1903
CFR Citation: 33 CFR 151.
Legal Deadline: None.
Abstract: The Coast Guard is proposing regulations to carry out the provisions of Annex VI of the MARPOL Protocol, which is focused on the prevention of air pollution from ships. The Act to Prevent Pollution from Ships has already given direct effect to most provisions of Annex VI, and the Coast Guard and the Environmental Protection Agency have carried out some Annex VI provisions through previous rulemakings. This proposed rulemaking would fill gaps in the existing framework for carrying out the provisions of Annex VI. Chapter 4 of Annex VI contains shipboard energy efficiency measures that include short-term measures reducing carbon emissions linked to climate change and supports Administration goals outlined in Executive Order 14008 titled Tackling the Climate Crisis at Home and Abroad. This proposed rulemaking would apply to U.S.-flagged ships. It would also apply to foreign-flagged ships operating either in U.S. navigable waters or in the U.S. Exclusive Economic Zone.

Statement of Need: The Coast Guard is proposing regulations to carry out the provisions of Annex VI of the MARPOL Protocol, which is focused on the prevention of air pollution from ships. The Act to Prevent Pollution from Ships has already given direct effect to most provisions of Annex VI, and the Coast Guard and the Environmental Protection Agency have carried out some Annex VI provisions through previous rulemakings. This proposed rule would fill gaps in the existing framework for carrying out the provisions of Annex VI and explain how the United States has chosen to carry out certain discretionary aspects of Annex VI. This proposed rule would apply to U.S.-flagged ships. And it would also apply to foreign-flagged ships operating in U.S. navigable waters or in the U.S. Exclusive Economic Zone.


Alternatives:

Alternative 1—No Action. USCG considered taking no action, but 33 U.S.C. 1903(c)(1) directs the DHS Secretary to prescribe any regulations necessary or desired regulations to carry out the provisions of the MARPOL Protocol. We have determined that it is necessary for the Coast Guard to issue regulations to implement Annex VI. Therefore, if we take no action, the Coast Guard having been delegated this rulemaking authority from the DHS Secretary would not fulfill its mandate from Congress to implement Annex VI.

Alternative 2—USCG considered not pursuing a rulemaking and allowing the Annex VI International Air Pollution Prevention (IAPP) certificate provision (Regulation 6) to be a mechanism to ensure compliance with Annex VI. We did not follow this alternative because not all ships subject to Annex VI would be required to obtain an IAPP certificate.

Alternative 3—USCG considered issuing only regulations that were required to explain how the United States planned to exercise its discretion under Annex VI, but we determined that additional regulations were necessary to clarify how we would be implementing Annex VI. The intent of these clarifying regulations (e.g., how will a vessel that does not have a GT ITC measurement know if it will be subject to surveys under Regulation 5.1) is not to impose any additional burden— for it is APPS that requires compliance with Annex VI, but to make implementation of Annex VI more effective, efficient, and transparent.

Anticipated Cost and Benefits: USCG anticipates the costs for the proposed rule to come primarily from additional labor for 5 requirements including overseeing surveys; developing and maintaining a fuel-switching procedure; recording various data during each fuel switching; developing and managing a Volatile organic compounds (VOC) management plan; crew member to calculate and report the attained Energy Efficient Design Index (EEDI) of the vessel, and crew member to develop and maintain the Ship Energy Efficiency Management Plan (SEEMP). USCG estimates that the requirement will total approximately $2 million over a ten year period.

USCG expects the proposed rule to have unquantified benefits from reduction in fatalities and injuries due to pollutant in engine emissions, and also reduced risk of retaliation due to breaching international agreement.

Timeline:

Regulatory Flexibility Analysis Required: No.
Government Levels Affected: None.
Federalism: Undetermined.
RIN: 1625–AC78

DHS—U.S. CUSTOMS AND BORDER PROTECTION (USCBP)

Proposed Rule Stage

87. Advance Passenger Information System: Electronic Validation of Travel Documents

Priority: Other Significant.
Legal Authority: 49 U.S.C. 44909; 8 U.S.C. 1221
CFR Citation: 19 CFR 122.
Legal Deadline: None.
Abstract: U.S. Customs and Border Protection (CBP) regulations require commercial air carriers to electronically transmit passenger information to CBP’s Advance Passenger Information System (APIS) prior to an aircraft’s arrival in or departure from the United States. CBP proposes to amend these regulations to incorporate additional carrier requirements that will enable CBP to validate each passenger’s travel documents prior to the passenger boarding the aircraft. This proposed rule would also require air carriers to transmit additional data elements through APIS for all commercial aircraft passengers arriving in the United States in order to support border operations and national security. The collection of additional data elements will support the efforts of the Centers for Disease Control, within the Department of Health and Human Services, to monitor and contract-trace health incidents.

Statement of Need: Current regulations require U.S. citizens and foreign travelers entering and leaving the United States via air travel to submit travel documents containing biographical information, such as a passenger’s name and date of birth. For security purposes, CBP compares the information on passengers’ documents to various databases and the terrorist watch list through APIS and recommends that air carriers deny boarding to those deemed inadmissible.
To further improve CBP’s vetting processes with respect to identifying and preventing passengers with fraudulent or improper documents from traveling or leaving the United States, CBP proposes to require carriers to receive from CBP a message that would state whether CBP matched the travel documents of each passenger to a valid, authentic travel document prior to departure to the United States from a foreign port or place or departure from the United States. The proposed rule also would require carriers to submit passenger contact information while in the United States to CBP through APIS. Submission of such information would enable CBP to identify and interdict individuals posing a risk to border, national, and aviation safety and security more quickly. Collecting these additional data elements would also enable CBP to further assist CDC to monitor and trace the contacts of those involved in serious public health incidents upon CDC request.

Additionally, the proposed rule would allow carriers to include the aircraft tail number in their electronic messages to CBP and make technical changes to conform with current practice.

**Anticipated Cost and Benefits:** The proposed rule would result in additional opportunity costs of time to CBP, air carriers, and passengers for coordination required to resolve a passenger’s status should there be a security issue. In addition, CBP has incurred costs for technological improvements to its systems. CBP, air carriers, and passengers would benefit from reduced passenger processing times during customs screening. Unquantified benefits would result from greater efficiency in passenger processing pre-flight, improved national security, and fewer penalties for air carriers following entry denial of a passenger.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No.

**Government Levels Affected:** None.

**Agency Contact:** Robert Neumann, Program Manager, Office of Field Operations, Department of Homeland Security, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Washington, DC 20229, Phone: 202 412–2788, Email: robert.m.neumann@cbp.dhs.gov.

**RIN:** 1651–AB43

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**DHS—USCBP**

**Final Rule Stage**

**88. Automation of CBP Form I–418 for Vessels**

**Priority:** Other Significant.


**CFR Citation:** 8 CFR 251.1; 8 CFR 251.3; 8 CFR 251.5; 8 CFR 258.2; 19 CFR 4.7 and 4.7a; 19 CFR 4.50; 19 CFR 4.81; 19 CFR 4.85; 19 CFR 4.91.

**Legal Deadline:** None.

**Abstract:** This rule amends the Department of Homeland Security’s regulations regarding the submission of U.S. Customs and Border Protection Form I–418, Passenger List—Crew List (Form I–418). Currently, the master or agent of every commercial vessel arriving in the United States, with limited exceptions, must submit a paper Form I–418, along with certain information regarding longshore work, to CBP at the port where immigration inspection is performed. Most commercial vessel operators are also required to submit a paper Form I–418 to CBP at the final U.S. port prior to departing for a foreign port. Under this rule, most vessel operators would be required to electronically submit the data elements on Form I–418 to CBP through the National Vessel Movement Center in lieu of submitting a paper form. This rule would eliminate the need to file the paper Form I–418 in most cases. This will result in an opportunity cost savings for vessel operators as well as a reduction in their printing and storage costs. CBP no longer needs this information as it is receiving it from the Coast Guard.

**Statement of Need:** Currently, the master or agent of every commercial vessel arriving in the United States, with limited exceptions, must submit Form I–418, along with certain information regarding longshore work, in paper form to CBP at the port where immigration inspection is performed. Most commercial vessel operators are also required to submit a paper Form I–418 to CBP at the final U.S. port prior to departing for a foreign place. Alternative, most vessel operators are required to electronically submit the same information to the U.S. Coast Guard (USCG) prior to arrival into a U.S. port. Under this rule, vessel operators will be required to electronically submit the data elements on Form I–418 to CBP through an electronic data interchange system (EDI) approved by CBP in lieu of submitting a paper form. This rule will streamline vessel arrival and departure processes by providing for the electronic submission of the information collected on the Form I–418, eliminating redundant data submissions, simplifying vessel inspections, and automating recordkeeping.

**Anticipated Cost and Benefits:** This rule will automate the Form I–418 process for all commercial vessel operators and eliminate the regulatory guidelines in place regarding the submission and retention of paper Form I–418s. These changes will generally not introduce new costs to commercial vessel operators, but they will introduce some costs to CBP. If vessel operators request a copy of their stamped and annotated electronic Form I–418, which they receive by paper now for CBP processing, they will incur negligible costs to do so. CBP will incur technology and printing costs from the Form I–418 Automation regulatory program, including costs to maintain mobile devices for real-time, electronic processing, and to print the paper Form I–418 until the admissibility inspection process is completely paperless.

However, this rule will provide considerable benefits and cost savings to both vessel operators and CBP. Following this rule’s implementation, vessel operators will enjoy cost savings from forgone paper Form I–418 submissions and form printing. CBP will experience a cost savings from the rule’s avoided printing, streamlined mobile post-inspection processing and electronic recordkeeping. In turn, CBP may dedicate these cost savings to other agency mission areas, such as improving border security or facilitating trade.

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**Regulatory Flexibility Analysis Required:** No.

**Government Levels Affected:** None.

**Agency Contact:** Brian Sale, Branch Chief, Manifest & Conveyance Security Division, Cargo & Conveyance, Office of Field Operation, Department of Homeland Security, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Washington, DC 20229, Phone: 202 325–3338, Email: brian.a.sale@cbp.dhs.gov; ofo-manifestbranch@cbp.dhs.gov.

**RIN:** 1651–AB18
DHS—TRANSPORTATION SECURITY ADMINISTRATION (TSA)

Proposed Rule Stage

89. Vetting of Certain Surface Transportation Employees


Unfunded Mandates: Undetermined.

Legal Authority: 49 U.S.C. 114; Pub. L. 110–53, secs. 1411, 1414, 1512, 1520, 1522, and 1531

CFR Citation: Not Yet Determined.

Legal Deadline: Other, Statutory, August 3, 2008, Background and immigration status check for all public transportation frontline employees is due no later than 12 months after date of enactment.

Sections 1411 and 1520 of Public Law 110–53, Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act), (121 Stat. 266, Aug. 3, 2007), require background checks of frontline public transportation and railroad employees not later than one year from the date of enactment. Requirement will be met through regulatory action.

Abstract: The 9/11 Act requires vetting of certain railroad, public transportation, and over-the-road bus employees. Through this rulemaking, the Transportation Security Administration (TSA) intends to propose the standards and procedures to conduct the required vetting. This regulation is related to 1652–AA55.

Security Training for Surface Transportation Employees.

Statement of Need: Employee vetting is an important and effective tool for averting or mitigating potential attacks by those with malicious intent who may target surface transportation and plan or perpetrate actions that may cause significant injuries, loss of life, or economic disruption.

Anticipated Cost and Benefits: TSA is in the process of determining the costs and benefits of this rulemaking.

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Regulatory Flexibility Analysis

Required: Undetermined.

Government Levels Affected: Undetermined.


URL For Public Comments: www.regulations.gov.

Agency Contact: Victor Parker, Transportation Security Specialist, Department of Homeland Security.

DHS—TSA

90. Indirect Air Carrier Security


CFR Citation: 49 CFR 1548.

Legal Deadline: None.

Abstract: The Transportation Security Administration (TSA) is reducing the frequency of renewal applications for indirect air carriers (IACs). Currently, these entities must submit an application to renew their security program each year. Following a review of TSA’s regulatory requirements seeking to reduce the cost of compliance, TSA determined that the duration of the security program for these entities can be increased from one year to three years without having a negative impact on transportation security.

Statement of Need: Consistent with Executive Order 12866 and OMB Circular A–4, TSA identified portions of air cargo regulations that may be tailored to impose a lesser burden on society and that may improve government processes. Under 49 CFR 1348 indirect air carriers are required to renew their security programs each year. TSA’s robust inspection and compliance requirements make the annual renewal requirement unnecessary.

DHS—TSA

91. Flight Training Security

Priority: Other Significant.


CFR Citation: 49 CFR 1552.

Legal Deadline: Final, Statutory, February 10, 2004, sec. 612(a) of Vision 100 requires the Transportation Security Administration (TSA) to issue an interim final rule within 60 days of enactment of Vision 100.

Requires the TSA to establish a process to implement the requirements of section 612(a) of Vision 100–Century of Aviation Reauthorization Act (Pub. L. 108–176, 117 Stat. 2490, Dec. 12, 2003), including the fee provisions, not later than 60 days after the enactment of the Act.

Abstract: An Interim Final Rule (IFR) published and effective on September 20, 2004, created a new part 1552, Flight Schools, in title 49 of the Code of Federal Regulations (CFR). This IFR applies to flight schools and to individuals who apply for or receive flight training. Flight schools are required to notify TSA when noncitizens, and other individuals designated by TSA, apply for flight training or recurrent training. TSA subsequently issued exemptions and interpretations in response to comments on the IFR, questions raised during operation of the program since 2004, and a notice extending the comment
period on May 18, 2018. Based on the comments and questions received, TSA is finalizing the rule with modifications, and considering modifications that would change the frequency of security threat assessments from a high-frequency event-based interval to a time-based interval, clarify the definitions and other provisions of the rule, and enable industry to use TSA-provided electronic recordkeeping systems for all documents required to demonstrate compliance with the rule.

Statement of Need: In the years since TSA published the IFR, members of the aviation industry, the public, and Federal oversight organizations have identified areas where the Flight Training Security Program (formerly the Alien Flight Student Program) could be improved. TSA’s internal procedures and processes for vetting applicants have also improved and advanced.

Publishing a final rule that addresses external recommendations and aligns with modern TSA vetting practices would streamline the Flight Training Security Program application, vetting, and recordkeeping process for all parties involved.

Anticipated Cost and Benefits: TSA is considering revising the requirements of the Flight Training Security Program to reduce costs and industry burden. One action TSA is considering is an electronic recordkeeping platform where all flight providers would upload certain information to a TSA-managed website. Also at industry’s request, TSA is considering changing the interval for a security threat assessment of each noncitizen flight student, eliminating the requirement for a security threat assessment for each separate training event. This change would result in an annual savings, although there may be additional start-up and record retention costs for the agency as a result of these revisions. The benefits of these actions would be immediate cost savings to flight schools and noncitizen students without compromising the security profile.

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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: None.


URL For Public Comments: www.regulations.gov.

Agency Contact: Johannes Knudsen, Program Manager, Alien Flight Student Program, Department of Homeland Security, Transportation Security Administration, Intelligence and Analysis, 6595 Springfield Center Drive, Springfield, VA 20598–6010, Phone: 571 227–2188, Email: johannes.knudsen@tsa.dhs.gov.

Alex Moscoso, Chief Economist, Economic Analysis Branch—Coordination & Analysis Division, Department of Homeland Security, Transportation Security Administration, Policy, Plans, and Engagement, 6595 Springfield Center Drive, Springfield, VA 20598–6028, Phone: 571 227–5839, Email: alex.moscoso@tsa.dhs.gov.

David Ross, Attorney–Advisor, Regulations and Security Standards, Department of Homeland Security, Transportation Security Administration, Chief Counsel’s Office, 6595 Springfield Center Drive, Springfield, VA 20598–6010, Phone: 571 227–2465, Email: david.ross18@tsa.dhs.gov.


DHS—TSA

Long-Term Actions

92. Surface Transportation Cybersecurity Measures


Unfunded mandates: Undetermined.

Legal Authority: 49 U.S.C. 114

CFR Citation: 49 CFR 1570.

Legal Deadline: None.

Abstract: On July 28, 2021, the President issued the National Security Memorandum on Improving Cybersecurity for Critical Infrastructure Control Systems. Consistent with this priority of the Administration and in response to the ongoing cybersecurity threats to pipeline systems, TSA used its authority under 49 U.S.C. 114 to issue security directives to owners and operators of TSA-designated critical pipelines that transport hazardous liquids and natural gas to implement a number of urgently needed protections against cyber intrusions. The first directive, issued in May 2021, requires critical owner/operators to (1) Report confirmed and potential cybersecurity incidents to the Cybersecurity and Infrastructure Security Agency (CISA); (2) designate a Cybersecurity Coordinator to be available 24 hours a day, seven days a week; (3) review current cybersecurity practices; and (4) identify any gaps and related remediation measures to address cyber-related risks and report the results to TSA and CISA within 30 days of issuance of the SD. A second security directive issued in July requires these owners and operators to (1) Implement specific mitigation measures to protect against ransomware attacks and other known threats to information technology and operational technology systems; (2) develop and implement a cybersecurity contingency and recovery plan; and (3) conduct a cybersecurity architecture design review. TSA is committed to enhancing and sustaining cybersecurity and intends to issue a rulemaking that will codify certain requirements with respect to pipeline and certain other surface modes.

Statement of Need: This rulemaking is necessary to address the ongoing cybersecurity threat to U.S. transportation modes.
DEPORTATION OR REMOVAL

Form I–246, Application for a Stay of
93. Fee Adjustment for U.S.
CUSTOMS ENFORCEMENT (USICE)
DHS—U.S. IMMIGRATION AND
Security, Transportation Security
Agency Contact: Scott Gorton,
Executive Director, Surface Policy
Division, Department of Homeland
Security, Transportation Security
Administration, Policy, Plans, and
Engagement, 6595 Springfield Center
Drive, Springfield, VA 20598–6002,
Phone: 571 227–1251, Email: tsa-
surface@tsa.dhs.gov.
RIN: 1653–AA82

DHS—U.S. IMMIGRATION AND
CUSTOMS ENFORCEMENT (USICE)
Proposed Rule Stage
93. Fee Adjustment for U.S.
Immigration and Customs Enforcement
Form I–246, Application for a Stay of
Deportation or Removal

Priority: Other Significant.
Legal Authority: 8 U.S.C. 1231; 8
U.S.C. 1356(m); 42 U.S.C. 4001 et seq.
CFR Citation: 44 CFR 59.1; 44 CFR
60.3(d)[3]; 44 CFR 64.3(a)[1].
Legal Deadline: None.
Abstract: The Department of
Homeland Security, U.S. Immigration
and Customs Enforcement (ICE) will
propose to adjust the fee for ICE Form
I–246, Application for a Stay of
Deportation or Removal. ICE has
determined that the current fee does not
fully recover the costs incurred to
perform the full range of activities
associated with determining if a
noncitizen ordered deported or removed
from the United States is eligible to
obtain a stay of deportation or removal.

Statement of Need: ICE has
determined that the current fee for Form
I–246 does not fully recover the costs
incurred to perform the full range of
activities associated with determining if a
foreign national ordered deported or removed
from the United States is eligible to
obtain a stay of deportation or removal.

Anticipated Cost and Benefits: ICE is
in the process of assessing the impacts of
this rule. The rule would increase the
fee for foreign nationals applying for a
stay of deportation or removal with the
Form I–246. The fee adjustment would
result in an increase in transfers from
foreign nationals to ICE.

Timetable:

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Regulatory Flexibility Analysis
Required: Undetermined.
Agency Contact: Sharon Hageman,
Acting Deputy Assistant Director,
Department of Homeland Security, U.S.
Immigration and Customs Enforcement,
500 12th Street SW, Mail Stop 5006,
Washington, DC 20536, Phone: 202 732–
6960, Email: ice.regulations@ice.dhs.gov.
RIN: 1653–AA82

DHS—FEDERAL EMERGENCY
MANAGEMENT AGENCY (FEMA)
Prerule Stage
94. • RFI National Flood Insurance
Program’s Floodplain Management
Standards for Land Management & Use,
& an Assessment of the Program’s
Impact on Threatened and Endangered
Species & Their Habitats

Priority: Other Significant.
Legal Authority: 42 U.S.C. 4001 et seq.
CFR Citation: 44 CFR 59.1; 44 CFR
60.3(d)[3]; 44 CFR 64.3(a)[1].
Legal Deadline: None.
Abstract: The Federal Emergency
Management Agency (FEMA) is issuing
this Request for Information to receive
the public’s input on two topics. First,
FEMA seeks the public’s input on
revising the National Flood Insurance
Program’s (NFIP) floodplain
management standards for land
management and use regulations to
better align with the current
understanding of flood risk and flood
risk reduction approaches. Specifically,
FEMA is seeking input from the public
on the floodplain management standards
that communities should adopt to result in safer, stronger, and
more resilient communities.
Additionally, FEMA seeks input on how the NFIP can better promote protection of
and minimize any adverse impact to
threatened and endangered species,
and their habitats.

Statement of Need: FEMA is issuing
this Request for Information to seek
information from the public on the
agency’s current floodplain management
standards to ensure the agency receives
public input as part of the agency’s
regular review of programs, regulations,
and policies, and to inform any action
to revise the NFIP minimum floodplain
management standards. FEMA also
plans to re-evaluate the implementation
of the NFIP under the Endangered
Species Act at the national level to
complete a revised Biological
Evaluation re-examining how NFIP
actions influence land development
decisions; the potential for such actions
to have adverse effects on threatened
and endangered species and critical
habitats; and to identify program
changes that would prevent jeopardy to
threatened and endangered species,
and/or destruction or adverse
modification of designated critical
habitats, as well as to promote the
survival and recovery of threatened
and endangered species. As a result, FEMA
also requests input from the public on
what measures the NFIP can take to
further protect and minimize any
adverse impacts to threatened and
endangered species and their habitat.

Anticipated Cost and Benefits: DHS is
currently considering the specific cost
and benefit impacts of the proposed
provisions.

Timetable:

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| Request for Infor-
mation. | 10/12/21 | 86 FR 56713 |
| Announcement of
Public Meetings. | 10/28/21 | 86 FR 59745 |
| Announcement of
Additional Pub-
lic Meeting: Ex-
tension of Com-
ment Period. | 11/22/21 | 86 FR 66329 |
| Request for Infor-
mation Com-
ment Period End. | 01/27/22 | |

Regulatory Flexibility Analysis
Required: No.
Government Levels Affected: None.
Additional Information: Docket ID
URL For More Information: http://
www.regulations.gov.
URL For Public Comments: http://
www.regulations.gov.
Agency Contact: Rachel Sears, Federal
Insurance and Mitigation
Administration, Department of
Homeland Security, Federal Emergency
Management Agency, 400 C Street SW,
Washington, DC 20472, Phone: 202 646–
2977, Email: fema-regulations@fema.dhs.gov.
RIN: 1660–AB11

DHS—FEMA
Proposed Rule Stage
95. National Flood Insurance Program:
Standard Flood Insurance Policy,
Homeowner Flood Form

Priority: Other Significant. Major
under 5 U.S.C. 801.
Anticipated Cost and Benefits: FEMA estimates that this rulemaking would result in an increase in transfer payments from policyholders to FEMA and insurance providers in the form of flood insurance premiums, and from FEMA to policymakers in the form of claims payments. Additionally, this rulemaking would result in benefits to policyholders, insurance providers, and FEMA, mostly through cost savings due to increased clarity and expanded coverage options. It would also help the NFIP better signal risk through premiums, reduce the need for Federal assistance, and increase resilience by enhancing mitigation efforts. Lastly, one increase in costs for FEMA will be for expenditures on implementation and familiarization of the rule.

Timetable:

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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: None.


DHS—FEMA

Final Rule Stage

96. • Amendment to the Public Assistance Program’s Simplified Procedures Large Project Threshold

Priority: Other Significant.

Legal Authority: 42 U.S.C. 5189

CFR Citation: 44 CFR 206.203(c)(1); 44 CFR 206.203(c)(2).

Legal Deadline: Final Statutory, February 26, 2014. Every 3 years; the President, acting through the Administrator, shall review the threshold for eligibility under section 422 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

Abstract: The Federal Emergency Management Agency (FEMA) is revising its regulations governing the Public Assistance program to update the monetary threshold at or below which FEMA will obligate funding based on an estimate of project costs, and above which FEMA will obligate funding based on actual project costs. This rule will ensure FEMA and recipients can more efficiently process unobligated

property owned by the insured condominium association. Individual unit owners must purchase their own Dwelling Form policy in order to insure their own contents.

FEMA last substantively revised the SFIP in 2000. See 65 FR 60758 (Oct. 12, 2000). In 2020, FEMA published a final rule that made non-substantive clarifying and plain language improvements to the SFIP. See 85 FR 43946 (July 20, 2020). However, many policyholders, agents, and adjusters continue to find the SFIP difficult to read and interpret compared to other, more modern, property and casualty insurance products found in the private market. Accordingly, FEMA proposes to adopt a new Homeowner Flood Form.

The new Homeowner Flood Form, which FEMA proposes to adopt to its regulations at 44 CFR 61 appendix A(4), would protect property owners in a one-to-four family residence. Upon adoption, the Homeowner Flood Form would replace the Dwelling Form as a source of coverage for this class of residential properties. FEMA would continue to use the Dwelling Form to insure landlords, renters, and owners of mobile homes, travel trailers, and condominium units. Compared to the current Dwelling Form, the new Homeowner Flood Form would clarify coverage and more clearly highlight conditions, limitations, and exclusions in coverage as well as add and modify coverages and coverage options. FEMA also proposes adding to its regulations five endorsements to accompany the new Form: Increased Cost of Compliance Coverage, Actual Cash Value Loss Settlement, Temporary Housing Expense, Basement Coverage, and Builder’s Risk. These endorsements, which FEMA proposes to codify at 44 CFR 61 appendices A(101)–(105), respectively, would give policyholders the option of amending the Homeowner Flood Form to modify coverage with a commensurate adjustment to premiums charged. Together, the Homeowner Flood Form and accompanying endorsements would increase options and coverage for owners of one-to-four family residences.

FEMA intends that this new Form will be more user-friendly and comprehensible. As a result, the new Homeowner Flood Form and its accompanying endorsements would provide a more personalized, customizable product than the NFIP has offered during its 50 years. In addition to aligning with property and casualty homeowners’ insurance and provide increased options and coverage in a more user-friendly and comprehensible format.

The new Homeowner Flood Form, which FEMA proposes to adopt to its regulations at 44 CFR 61 appendix A(4), would protect property owners in a one-to-four family residence. Upon adoption, the Homeowner Flood Form would replace the Dwelling Form as a source of coverage for this class of residential properties. FEMA would continue to use the Dwelling Form to insure landlords, renters, and owners of mobile homes, travel trailers, and condominium units. Compared to the current Dwelling Form, the new Homeowner Flood Form would clarify coverage and more clearly highlight conditions, limitations, and exclusions in coverage as well as add and modify coverages and coverage options. FEMA also proposes adding to its regulations five endorsements to accompany the new Form: Increased Cost of Compliance Coverage, Actual Cash Value Loss Settlement, Temporary Housing Expense, Basement Coverage, and Builder’s Risk. These endorsements, which FEMA proposes to codify at 44 CFR 61 appendices A(101)–(105), respectively, would give policyholders the option of amending the Homeowner Flood Form to modify coverage with a commensurate adjustment to premiums charged. Together, the Homeowner Flood Form and accompanying endorsements would increase options and coverage for owners of one-to-four family residences.

FEMA intends that this new Form will be more user-friendly and comprehensible. As a result, the new Homeowner Flood Form and its accompanying endorsements would provide a more personalized, customizable product than the NFIP has offered during its 50 years. In addition to aligning with property and casualty homeowners’ insurance and provide increased options and coverage in a more user-friendly and comprehensible format,
Project Worksheets for COVID–19 declarations, which continue to fund important pandemic-related work, while avoiding unnecessary confusion and administrative burden by not affecting previous project size determinations.

Statement of Need: FEMA’s Public Assistance (PA) program provides grants to State, local, Tribal, and Territorial governments, as well as eligible private nonprofit (PNP) organizations, for debris removal, emergency protective measures, and the repair, replacement, or restoration of disaster-damaged facilities after a Presidential-declared major disaster. FEMA categorizes each grant award as either a small or large project, which is determined by a monetary threshold set each year by FEMA pursuant to statute. (See section 422 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, codified at 42 U.S.C. 5189). FEMA obligates money for a small project based on an estimate of the project costs, and FEMA obligates money for a large project based on actual project costs as the project progresses and cost documentation is provided to FEMA. This expedites FEMA’s processing of PA grant funding by eliminating much of the administrative burden that FEMA experiences when awarding projects at or above the threshold (i.e., large projects). Ultimately, this reduces FEMA’s cost of administering PA funding and allows FEMA to expedite its provision of Federal disaster assistance.

In 2013, the Sandy Recovery Improvement Act amended section 422(b) of the Stafford Act and required FEMA to complete an analysis to determine whether an increase in the large project threshold was appropriate. Following this analysis, in 2014 FEMA updated the maximum threshold from $68,500 to $120,000 and continued to adjust the threshold annually to reflect changes in the Consumer Price Index, as required under section 422(b)(2). Section 422(b)(3) requires FEMA to review the threshold every three years. FEMA conducted an analysis in 2017 and recommended no change to the threshold at that time. As a result, the maximum threshold for Fiscal Year (FY) 2021 is currently set at $132,800.

Since FEMA’s analysis in 2017, the U.S. has seen increased disaster activity either due to, or amplified or aggravated by, the climate crisis. For example, in 2017, Hurricanes Harvey, Irma, and Maria caused a combined total of $293.6 billion in damages. Damages from wildfires in that year and the next totaled approximately $61 billion. In 2020, FEMA responded to 22 one-billion-dollar events the highest in its history which included a record number of tropical storms in the Atlantic and the Nation’s most active wildfire year recorded. The estimated damages from these 22 events totaled approximately $95 billion. In addition to increased natural disasters, in 2020 FEMA also issued an unprecedented 57 major disaster declarations in response to COVID–19, including for every State, 5 territories, the Seminole Tribe of Florida, and the District of Columbia. In FY 2020 declarations, FEMA’s funding under the PA program is over $32 billion. Although costs for COVID–19 accounted for 94 percent of this funding, FEMA expects climate change to make natural disasters more frequent and more destructive, requiring greater spending on recovery in the future.

As a result, in 2020, FEMA conducted another analysis to ensure that FEMA is maximizing the benefits of simplified procedures in light of its more recent disaster spending. Based on this analysis, FEMA determined that it should increase the threshold to $1,000,000, with continued annual adjustment for inflation based on the Consumer Price Index.

Anticipated Cost and Benefits: FEMA estimates that this rulemaking would result in transfers from FEMA to PA recipients and familiarization costs for PA applicants. Additionally, this rule would reduce the administrative burden and improve program efficiency for PA recipients, subrecipients, and FEMA, resulting in cost savings to FEMA and PA recipients/subrecipients.

Timetable:

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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: Federal, Local, State, Tribal.

Agency Contact: Valerie Boulet, Program Administration Section, Public Assistance Division, Department of Homeland Security, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472–3100, Phone: 202 538–3860, Email: valerie.boulet@fema.dhs.gov.

RIN: 1660–AB10

DHS—FEMA

Long-Term Actions

97. Individual Assistance Program Equity


Unfunded Mandates: Undetermined.

Legal Authority: 42 U.S.C. 5155; 42 U.S.C. 5174; 42 U.S.C. 5189a


Legal Deadline: None.

Abstract: As climate change results in more frequent and/or intense extreme weather events like severe storms, flooding and wildfires, disproportionately impacting the most vulnerable in society and in furtherance of E.O. 13895, the Federal Emergency Management Agency (FEMA) proposes to amend its Individual Assistance (IA) regulations to increase equity and ease of entry to the IA Program. To provide a full opportunity for underserved communities to participate, FEMA proposes to amend application of ‘safe, sanitary, and functional’ for IA repair assistance; re-evaluate the requirement to apply for a Small Business Administration loan prior to receipt of Other Needs Assistance; add eligibility criteria for its Serious Needs & Displacement Assistance; amend its requirements for Continued Temporary Housing Assistance; re-evaluate its approach to insurance proceeds; and amend its appeals process. FEMA also proposes revisions to reflect changes to statutory authority that have not yet been implemented in regulation, to include provisions for utility and security deposit payments, lease and repair of multi-family rental housing, childcare assistance, and maximum assistance limits.

Statement of Need: FEMA’s Individuals and Households Program (IHP) regulations have not had a major review and update since section 206 of the Disaster Mitigation Act of 2000 replaced the Individual and Family Grant Assistance Program with the current IHP. Some minor changes to Repair Assistance were completed in 2013, but Congress has passed multiple other laws that have superseded portions of the regulations and created other programs or forms of assistance with no supporting regulations. FEMA proposes an update to the IHP regulations now to bring them up to date and address lessons learned through the course of implementing the IHP in disasters much larger than any
Program 98. Ammonium Nitrate Security Proposed Rule Stage

INFRASTRUCTURE SECURITY

DHS—CYBERSECURITY AND INFRASTRUCTURE SECURITY AGENCY (CISA)

Proposed Rule Stage

98. Ammonium Nitrate Security Program

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Regulatory Flexibility Analysis

Required: Undetermined.

Government Levels Affected: Undetermined.


RIN: 1660–AB07

Anticipated Cost and Benefits: In the 2011 NPRM, CISA estimated cost of this proposed rule would range from $300 million to $1,041 million over 10 years at a 7 percent discount rate. In the intervening years, CISA has adjusted its approach to this rulemaking and has made significant changes to the way we estimate the costs associated with this SNPRM. At this time CISA is still developing the cost estimates for and substantive contents of this SNPRM.

Summary of Legal Basis: This regulation is statutorily mandated by 6 U.S.C. 488 et seq.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Statement of Regulatory Priorities for Fiscal Year 2022

Introduction

The Regulatory Plan for the Department of Housing and Urban Development (HUD) for Fiscal Year (FY) 2022 highlights the most significant regulations and policy initiatives that HUD seeks to complete during the upcoming fiscal year. As the Federal agency that serves as the nation’s housing agency, HUD is committed to addressing the housing needs of all Americans by creating strong, sustainable, inclusive communities, and quality affordable homes for all. As a result, HUD plays a significant role in the lives of families and in communities throughout America.

HUD is currently working to strengthen the housing market to bolster the economy and protect consumers; meet the need for quality affordable rental homes; utilize housing as a platform for improving quality of life; build inclusive and sustainable communities free from discrimination and transform the way HUD does business. Under the leadership of Secretary Marcia L. Fudge, HUD is dedicated to implementing the Administration’s priorities by setting forth initiatives related to recovery from the COVID–19 pandemic, providing economic relief to those HUD serves, advancing racial equity and civil rights, and tackling the climate emergency.

Since the beginning of the Administration, HUD has taken a number of actions to advance equity in its programs and secure equal access to housing opportunity for all. For example, on February 11, 2021, HUD issued a memorandum directing its programs and policy initiatives to fully enforce the Fair Housing Act to prohibit discrimination based on sexual orientation and gender identity; on April 26, 2021, HUD issued a plan of action the Department will take to

Facilities register with the Department of Homeland Security and be vetted against the Terrorist Screening Database. The statute further requires that information about transactions of ammonium nitrate be recorded and kept. Given the widespread use of ammonium nitrate in many sectors of the economy, including industrial, agricultural, and consumer uses, the Department is exploring ways to reduce the threat of terrorism posed by ammonium nitrate while remaining sensitive to the impacts on the supply chain and legitimate users.

Regulatory Flexibility Analysis

Required: Yes.

Small Entities Affected: Businesses.

Government Levels Affected: Federal, Local, State.

Federalism: This action may have federalism implications as defined in E.O. 13132.


URL For Public Comments: www.regulations.gov.

Agency Contact: Ryan Donaghy, Deputy Branch Chief for Chemical Security Policy, Rulemaking, and Engagement, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency, 245 Murray Lane SW, Mail Stop 0610, Arlington, VA 20528, Phone: 571 532–4127, Email: ryan.donaghy@ cisa.dhs.gov.

Related RIN: Previously reported as 1601–AA52.

RIN: 1670–AA00

BILLING CODE 9110–9B–P
strengthen Nation-to-Nation relations and improve HUD-wide Tribal consultation; on June 10, 2021, HUD published an interim final rule to restore certain definitions and certifications to its regulations implementing the Fair Housing Act’s requirement to affirmatively further fair housing (AFFH) (86 FR 30779); and on June 25, 2021, HUD published a proposed rule to reinstate HUD’s discriminatory effects standard (86 FR 33590).

The rules highlighted in HUD’s regulatory plan for FY 2022 reflect HUD’s efforts to continue its work in meeting the needs of underserved communities and providing for equal access to housing opportunities. In addition, it reflects HUD’s efforts to strengthen the housing market and protect consumers, and to aid in recovery from the COVID–19 pandemic. Additionally, HUD notes that the FY 2022 Semiannual Regulatory Agenda includes additional rules that advance the Administration’s priorities, including, rules to advance equity by ensuring non-discrimination based on disability in HUD programs, and a rule to help address the climate emergency by improving the resilience of HUD-assisted or financed projects to the effect of climate change.

Affirmatively Furthering Fair Housing

Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” (86 FR 7009, January 20, 2021) requires each agency to consider whether new policies, regulations, or guidance documents may be necessary to advance equity in agency actions and programs. Further, on January 26, 2021 (86 FR 7487), President Biden issued a “Memorandum on Redressing Our Nation’s and the Federal Government’s History of Discriminatory Housing Practices and Policies,” which explained that the Federal Government will work with communities to, among other things, end housing discrimination, lift barriers that restrict housing and neighborhood choice, promote diverse and inclusive communities, and to secure equal access to housing opportunity for all.

As noted above, on June 10, 2021, HUD published an interim final rule to restore certain definitions and certifications to its regulations implementing the Fair Housing Act’s requirement. HUD will build on that rule and issue an AFFH proposed rule that seeks to ensure that HUD and its grantees are sufficiently effective in fulfilling the purposes and policies of the Fair Housing Act. HUD’s proposed rule will provide HUD and its program participants with a more effective Fair Housing Planning Process as a means to meet their duty to affirmatively further the Fair Housing Act. Currently, HUD funding recipients must certify compliance with their duty to AFFH on an annual basis and HUD itself has a continuous statutory obligation to ensure that the Fair Housing Act’s AFFH obligations are followed.

For decades, courts have held that the AFFH obligation imposes a duty on HUD and its grantees to affirmatively further the purposes of the Fair Housing Act. These courts have held that for funding recipients to meet their AFFH obligations they must, at a minimum, make decisions informed by preexisting racial and socioeconomic residential segregation. The courts have further held that, informed by such information, funding recipients must strive to dismantle historic patterns of racial segregation; preserve integrated housing that already exists; and otherwise take meaningful steps to further the Fair Housing Act’s purposes beyond merely refraining from taking discriminatory actions and banning others from such discrimination.

Through this proposed rule, HUD plans to implement the AFFH mandate and work towards a more equitable future for all by developing a Fair Housing Planning Process that reduces burdens for program participants and achieves material, positive change that affirmatively furthers fair housing. Specifically, HUD is focused on advancing equity and providing access to opportunity for underserved populations in a manner that is more effective in achieving measurable improvements while avoiding unnecessary burden.

Aggregate Costs and Benefits

Executive Order 12866, as amended, requires the agency to provide its best estimate of the combined aggregate costs and benefits of all regulations included in the agency’s Regulatory Plan that will be pursued in FY 2022. HUD expects that the neither the total economic costs nor the total efficiency gains will exceed $100 million. HUD grantees are already familiar with the AFFH compliance process as instituted by the 2015 rule and the 2021 interim final rule. Having learned from prior rulemakings, HUD believes that the rule will create the right balance of analysis so that grantees will have the available data necessary to help them in completing any analytical requirements without adding the same level of costs associated with the 2015 rulemaking.

Statement of Need

The rule is needed to conform HUD regulations with statutory standards and judicial interpretations of those standards, and to ensure consistency in fair housing certifications across HUD programs. This proposed rule would consider HUD’s AFFH rule published on July 16, 2015 (80 FR 42272) (2015 AFFH rule) but improve upon its framework and impose less regulatory burden.

Alternatives: Alternatives to promulgating this rule involve finalizing the interim rule, “Restoring Affirmatively Furthering Fair Housing Definitions and Certifications,” without taking further action or repromulgating the 2015 AFFH rule without considering changes that could reduce regulatory burden and enable a more meaningful fair housing planning process. If HUD were to finalize the interim rule without taking further action, there would be inconsistency in fair housing certifications across different jurisdictions, as the interim rule does not require that jurisdictions submit fair housing plans in any particular form, such as an Analysis of Impediments, or an Assessment of Fair Housing, as was previously required. If HUD were to repromulgate the 2015 AFFH rule without considering changes, HUD would miss an opportunity to improve upon that rule and reduce the significant regulatory burdens resulting from that rule. HUD believes neither of those options are better than providing for a new certification process that will undergo new public comment.

Risks: Previous iterations of the AFFH rule have resulted in an amount of burden on grantees that made implementation challenging. HUD must balance the use of data and the depth of analysis that is required of differing sized grantees to ensure that grantees can implement the affirmatively furthering fair housing mandate while continuing to fulfill their programmatic requirements. In promulgating this rule, HUD will attempt to secure support from as many stakeholders as possible to ensure maximum compliance with the duty to AFFH.

Timetable:

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wealth through homeownership. The difference between the monthly payment provided under a 40-year loan modification and a 30-year loan modification may be significant for a borrower and their ability to afford the modified payment.

Aggregate Costs and Benefits
Executive Order 12866, as amended, requires the agency to provide its best estimate of the combined aggregate costs and benefits of all regulations included in the agency’s Regulatory Plan that will be pursued in FY 2021. HUD expects that neither the total economic costs nor the total efficiency gains will exceed $100 million. This proposed rule would increase available loss mitigation options for borrowers and enable more borrowers to avoid foreclosure and remain in their homes. HUD also anticipates that this would have a positive effect on the FHA Mutual Mortgage Insurance Fund by lowering defaults.

Statement of Need
Borrowers impacted by the COVID–19 pandemic, including those who may re-default in the future after having received a loss mitigation option under HUD’s COVID–19 policies, may need a 40-year loan modification to provide a monthly payment that they can afford. It is vital that these borrowers receive any loss mitigation options at HUD’s disposal and for which they are eligible to avoid foreclosure whenever possible and to mitigate the impact of the COVID–19 pandemic.

Additionally, given the large number of FHA-insured mortgages that have been originated or refinanced in the past few years in a historically low interest rate environment, simply extending out the term of a mortgage in default for another 30 years at a similar interest rate would not provide a substantial reduction to a borrower’s monthly mortgage payment. Therefore, providing this option for relief for all borrowers and originators is prudent for all FHA-insured mortgages.

Alternatives
HUD has considered other loss mitigation options which would allow borrowers to avoid foreclosure in response to the COVID–19 pandemic. HUD has made many of these options available through mortgagee letter. HUD does not view these options as alternatives, as different circumstances may call for different forms of loss mitigation. Additionally, HUD finds that this new option should not be limited only in response to the COVID–19 pandemic, but should be available in all circumstances where it could help individuals keep their homes.

Risks
Although the impact of introducing a 40-year loan modification option for borrowers on the MMI Fund will needed to be modeled, HUD anticipates a favorable impact through reduced utilization of other, more costly loss mitigation options and foreclosure prevention.

Additionally, HUD anticipates that the effect on FHA-insured mortgagors will be minor. HUD recognizes that a 40-year mortgage would cost the borrower in the form of greater interest paid over time and slower equity building. However, HUD notes that the average life of an FHA-insured mortgage is approximately seven years, and HUD anticipates that a borrower would similarly refinance a 40-year mortgage. Any additional interest and slowed equity build that a borrower might pay with a 40-year modified loan compared to a 30-year modified loan, especially when looked at over the life of an average FHA-insured mortgage, would not impose a significant burden to borrowers and would be outweighed by the benefits to a borrower of being able to retain their home.

Timetable:

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Federalism Affected: No.
Energy Affected: No.
International Impacts: No.

HUD—OFFICE OF HOUSING (OH)
Proposed Rule Stage

99. Increased 40-Year Term for Loan Modifications (FR–6263)


CFR Citation: 24 CFR 203.
Legal Deadline: None.

Abstract: This would amend the current regulation at 24 CFR 203.616 to permit the modification of an FHA-insured mortgage for a maximum term not to exceed 480 months, or 40 years. The current regulation allows a
mortgagee to modify a loan to cure a default by recasting the total unpaid amount due and other eligible costs for a term not exceeding 360 months, or 30 years. Increasing the term length of a modified loan would provide borrowers with a deeper reduction to their monthly mortgage payments as the outstanding principal would be spread over a longer time frame. This change would provide more FHA borrowers with the ability to retain their homes after default, including borrowers who have exhausted their partial claim allocation, as well as provide more affordable housing payments. This change would also align FHA with modifications available to borrowers with mortgages backed by Fannie Mae or Freddie Mac, which currently provide a 40-year loan modification option.

Statement of Need: HUD anticipates that this would allow mortgagees greater ability to assist defaulted borrowers, including mortgagees affected by the COVID–19 pandemic, with avoiding foreclosure. It is vital that borrowers receive any loss mitigation options at HUD’s disposal and for which they are eligible to avoid foreclosure whenever possible and to mitigate the impact of a loss of job or other financial strains such as those resulting from the COVID–19 pandemic.

Additionally, given the large number of FHA-insured mortgages that have been originated or refinanced in the past few years in a historically low interest rate environment, simply extending out the term in default for another 30 years at a similar interest rate would not provide a substantial reduction to a borrower’s monthly mortgage payment. Therefore, providing this option for relief for all borrowers and originators is prudent for all FHA-insured mortgages.

Summary of Legal Basis: Executive Order 14002, Economic Relief Related to the COVID–19 Pandemic (Jan. 22, 2021), directs federal agencies to promptly identify actions they can take within existing authorities to address the current economic crisis resulting from the [COVID 19] pandemic. In response to this Executive Order and in support of the goal of achieving broad economic recovery following the COVID–19 pandemic, HUD has established expanded COIVD–19 Loss Mitigation Options to address the impacts many Americans are experiencing in recovering financially from the long-lasting effects of the pandemic.

Alternatives: HUD has considered other loss mitigation options which would allow borrowers to avoid foreclosure in response to the COVID–19 pandemic. HUD has made many of these options available through mortgagee letter. HUD does not view these options as alternatives, as different circumstances may call for different forms of loss mitigation. Additionally, HUD finds that this new option should not be limited only in response to the COVID–19 pandemic, but should be available in all circumstances where it could help individuals keep their homes.

Anticipated Cost and Benefits: Executive Order 12866, as amended, requires the agency to provide its best estimate of the combined aggregate costs and benefits of all regulations included in the agency’s Regulatory Plan that will be pursued in FY 2021. HUD expects that neither the total economic costs nor the total efficiency gains will exceed $100 million. This proposed rule would increase available loss mitigation options for borrowers and enable more borrowers to avoid foreclosure and remain in their homes. HUD also anticipates that this would have a positive effect on the FHA Mutual Mortgage Insurance Fund by lowering defaults.

Risks: Although the impact of introducing a 40-year loan modification option for borrowers on the MMI Fund will needed to be modeled, HUD anticipates a favorable impact through reduced utilization of other, more costly loss mitigation options and foreclosure prevention.

Additionally, HUD anticipates that the effect on FHA-insured mortgagees will be minor. HUD recognizes that a 40-year mortgage would cost the borrower in the form of great interest paid over time and slower equity building. However, HUD notes that the average life of an FHA-insured mortgage is approximately seven years, and HUD anticipates that a borrower would similarly refinance a 40-year mortgage. Any additional interest and slowed equity build that a borrower might pay with a 40-year modified loan compared to a 30-year modified loan, especially when looked at over the life of an average FHA-insured mortgage, would not impose a significant burden to borrowers and would be outweighed by the benefits to a borrower of being able to retain their home.

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Regulatory Flexibility Analysis

Required: No.
Small Entities Affected: No.
Government Levels Affected: None.


RIN: 2502–A759

HUD—OFFICE OF FAIR HOUSING AND EQUAL OPPORTUNITY (FHEO)

Proposed Rule Stage

100. Affirmatively Furthering Fair Housing (FR–6250)

Priority: Other Significant.

Legal Authority: 42 U.S.C. 3608(e)(5); 42 U.S.C. 5304; 42 U.S.C. 12705(b); 42 U.S.C. 1437c–1; 42 U.S.C. 3535(d); 42 U.S.C. 3600 to 3620

CFR Citation: 24 CFR 5, 91, 92, 570, 574, 576, and 903.

Legal Deadline: None.

Abstract: Through this proposed rule, HUD seeks to provide HUD and its program participants with a more effective means to affirmatively further the purposes and policies of the Fair Housing Act. The current procedures for affirmatively furthering fair housing carried out by program participants are not sufficiently effective to fulfill the purposes and policies of the Fair Housing Act. HUD will be seeking public comment on a new proposed rule that is focused on advancing equity and providing access to opportunity for underserved populations in a manner that is more effective in achieving measurable improvements while avoiding unnecessary burden.

Statement of Need: The rule is needed to conform HUD regulations with statutory standards and judicial interpretations of those standards, and to ensure consistency in fair housing certifications across HUD programs. This proposed rule would consider HUD’s AFFH rule published on July 16, 2015 (80 FR 42272) (2015 AFFH rule) but improve upon its framework and impose less regulatory burden.

Summary of Legal Basis: Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, (86 FR 7009, January 20, 2021) requires each agency to consider whether new policies, regulations, or guidance documents may be necessary to advance equity in agency actions and programs. Further, on January 26, 2021 (86 FR 7487), President Biden issued a Memorandum on Redressing Our Nation’s and the Federal Government’s History of Discriminatory Housing Practices and Policies, which explained...
that the Federal Government will work with communities to, among other things, end housing discrimination, lift barriers that restrict housing and neighborhood choice, promote diverse and inclusive communities, and secure equal access to housing opportunity for all.

**Alternatives:** Alternatives to promulgating this rule involve finalizing the interim rule, Restoring Affirmatively Furthering Fair Housing Definitions and Certifications, without taking further action or repromulgating the 2015 AFFH rule without considering changes that could reduce regulatory burden and enable a more meaningful fair housing planning process. If HUD were to finalize the interim rule without taking further action, there would be inconsistency in fair housing certifications across different jurisdictions, as the interim rule does not require that jurisdictions submit fair housing plans in any particular form, such as an Analysis of Impediments or an Assessment of Fair Housing, as was previously required. If HUD were to repromulgate the 2015 AFFH rule without considering changes, HUD would miss an opportunity to improve upon that rule and reduce the significant regulatory burdens resulting from that rule. HUD believes neither of those options are better than providing for a new certification process that will undergo new public comment.

**Anticipated Cost and Benefits:** Executive Order 12866, as amended, requires the agency to provide its best estimate of the total cumulative aggregate costs and benefits of all regulations included in the agency’s Regulatory Plan that will be pursued in FY 2022. HUD expects that the neither the total economic costs nor the total efficiency gains will exceed $100 million. HUD grantees are already familiar with the AFFH compliance process as instituted by the 2015 rule and the 2021 interim final rule. Having learned from prior rulemakings, HUD believes that the rule will create the right balance of analysis so that grantees will have the available data necessary to help them in completing any analytical requirements without adding the same level of costs associated with the 2015 rulemaking.

**Risks:** Previous iterations of the AFFH rule have resulted in an amount of burden on grantees that made implementation challenging. HUD must balance the use of data and the depth of analysis that is required of differing sized grantees to ensure that grantees can implement the affirmatively furthering fair housing mandate while continuing to fulfill their programmatic requirements. In promulgating this rule, HUD will attempt to secure support from as many stakeholders as possible to ensure maximum compliance with the duty to AFFH.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** No.

**Small Entities Affected:** No.

**Government Levels Affected:** Federal, Local, State.

**Agency Contact:** Demetria McCain, Principal Deputy Assistant Secretary for Fair Housing and Equal Opportunity, Department of Housing and Urban Development, Office of Fair Housing and Equal Opportunity, 451 Seventh Street, Washington, DC 20410, Phone: 202 402–5188.

**BILLING CODE 4210–67–P**

**UNITED STATES DEPARTMENT OF THE INTERIOR**

**Fall 2021 Regulatory Plan**

**Introduction**

The U.S. Department of the Interior (Department) is the principal steward of our Nation’s public lands and resources, including many of our cultural treasures. The Department serves as trustee to Native Americans, Alaska Natives, and Federally-Recognized Tribes and is responsible for our ongoing relationships with the island territories under U.S. jurisdiction and the freely associated states. Among the Department’s many responsibilities is managing more than 500 million surface acres of Federal land, which constitutes approximately 20 percent of the Nation’s land area, as well as approximately 700 million subsurface acres of Federal mineral estate, and more than 2.5 billion acres of submerged lands on the Outer Continental Shelf (OCS).

In addition, the Department protects and recovers endangered species; protects natural, historic, and cultural resources; provides scientific and other information about those resources; and manages water projects that are an essential lifeline and economic engine for many communities.

Hundreds of millions of people visit Department-managed lands each year to take advantage of a wide range of recreational pursuits—including camping, hiking, hunting, fishing, and various other forms of outdoor recreation—and to learn about our Nation’s history. Each of these activities supports local communities and their economies. The Department also provides access to Federal lands and offshore areas for the development of energy, minerals, and other natural resources that generate billions of dollars in revenue.

In short, the Department of the Interior plays a central role in how the United States stewards its public lands, ensures environmental protections, pursues environmental justice, honors the nation-to-nation relationship with tribes and the special relationships with other indigenous people and the insular areas.

**Regulatory and Deregulatory Priorities**

To help advance the Secretary of the Interior’s (Secretary) commitment to honoring the Nation’s trust responsibilities and to conserve and manage the Nation’s natural resources and cultural heritage, the Department’s regulatory and deregulatory priorities in the coming fiscal year (FY) will focus on:

- Tackling the Climate Crisis, Strengthening Climate Resiliency, and Facilitating the Transition to Renewable Energy;
- Upholding Trust Responsibilities to Federally-Recognized American Indian and Alaska Native Tribes Restoring Tribal Lands, and Protecting Natural and Cultural Resources Advancing Equity and Supporting Underserved Communities;
- Investing in Healthy Lands, Waters and Local Economies and Strengthening Conservation, and Protecting Endangered Species and their Habitat

**Tackling the Climate Crisis, Strengthening Climate Resiliency, and Facilitating the Transition to Renewable Energy**

In one of his first official actions after taking the oath of office on January 20, 2021, President Biden signed Executive Order (E.O.) 13990, entitled “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.” This Executive order established the Biden-Harris administration’s policy to “improve public health and protect our environment, to ensure access to clean air and water, to reduce greenhouse gas emissions and to bolster resilience of the impacts of climate change.” An accompanying document, entitled “Fact Sheet: List of Agency Actions for Review,” directed several Federal agencies, including the Department, to review various regulations in accordance with E.O. 13990, and that review will continue for FY 2022.
To help implement the commitment to tackling the climate crisis, Secretary Haaland signed her first Secretary’s Order (SO), SO 3398, entitled “Revocation of Secretary’s Orders Inconsistent with Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.” SO 3398 implements the review of Departmental actions mandated by Executive Order 13990. Foundational to this process is the commitment to science and transparency and a pledge “to conserve and restore our land, water, and wildlife; to reduce greenhouse gas emissions; to create jobs through a growing clean energy economy; and to bolster resilience to the impacts of climate change.” SO 3398 revoked 12 SOs that were issued between March 29, 2017, and December 22, 2020, and directed the Department to conduct reviews and take appropriate actions on certain regulations. The SO further directed Bureaus and Offices to review all policies and guidance documents that may warrant further action to be consistent with Executive Order 13990.

Recognizing the ongoing threat that climate change poses to our Nation and to the world, on January 27, 2021, President Biden also issued Executive Order 14008 entitled, “Tackling the Climate Crisis at Home and Abroad.” Executive Order 14008 directed Federal agencies to take a government-wide approach to the climate crisis and established a National Climate Task Force to facilitate the organization and deployment of such an approach.

To implement the directives in Executive Order 14008, on April 16, 2021, Secretary Haaland issued SO 3399, which directs a “Department-Wide Approach to the Climate Crisis and Restoring Transparency and Integrity to the Decision-Making Process.” SO 3399 established a Departmental Climate Task Force charged with developing a strategy to reduce climate pollution; improving and increasing adaptation and resilience to the impacts of climate change; addressing current and historic environmental injustice; protecting public health; and conserving Department-managed lands.

In accordance with Executive Orders 13990 and 14008, a number of bureaus in the Department are pursuing regulatory actions to implement these administration priorities. The Bureau of Land Management (BLM), for example, is proposing rules to ensure the responsible development of oil and gas on public lands, including “Waste Prevention, Production Subject to Royalties, and Resource Conservation 43 CFR parts 3160 and 3170” (1004–AE79), known as the Waste Prevention Rule, and “Revision of Existing Regulations Pertaining to Fossil Fuel Leases and Leasing Process 43 CFR parts 3100 and 3400” (1004–AE80), known as the Fossil Fuel Rule. The Waste Prevention Rule would reduce methane emissions in the oil and gas sector and mitigate impacts of climate change. The Fossil Fuel Rule would update BLM’s process for leasing to ensure the protection and proper stewardship of the public lands, including potential climate and other impacts associated with fossil fuel activities. Also, to comply with Executive Order 14008, BLM plans to complete a comprehensive review and reconsideration of Federal fossil fuel leasing practices considering BLM’s broad stewardship responsibilities over the public lands, including potential climate and other impacts associated with fossil fuel activities on public lands.

Similarly, the Bureau of Ocean Energy Management (BOEM) is also undertaking a comprehensive review and reconsideration of offshore Federal oil and gas permitting and leasing practices, including potential climate and other impacts associated with offshore oil and gas activities. The BOEM will evaluate the sources and impacts of climate change on the OCS, working in consultation with the Secretary of Agriculture, the Secretary of Commerce, through the National Oceanic and Atmospheric Administration, and the Secretary of Energy. Given the Secretary’s Outer Continental Shelf Lands Act (OCSLA) mandate to conserve the natural resources on the OCS, this initiative will evaluate the causes and effects of climate change and determine what appropriate measures BOEM should take to further control emissions of greenhouse gases, including whether to adjust royalties associated with coal, oil, and gas resources extracted from public lands and offshore waters, develop regulations, or to take other action to account for corresponding climate costs.

One of the key directions in Executive Order 14008 provides that the Secretary, in consultation with the heads of other relevant agencies, will review siting and permitting processes on public lands and in offshore waters to identify steps that can be taken, consistent with applicable law, to increase renewable energy production. The Department is committed to fully facilitating the development of renewable energy on public lands and waters, as well as supporting tribal and territorial efforts to develop renewable energy, including deploying 30 gigawatts (GW) of offshore wind by 2030 and 25GW of onshore renewable energy by 2025. This mandate is to be undertaken while also ensuring appropriate protection of public lands, waters, and biodiversity and creating good jobs.

As part of these efforts in FY 2022, BOEM will propose a rule entitled, “Renewable Energy Modernization Rule” (1010–AE04), that will substantially update the existing renewable energy regulations to facilitate responsible development of renewable energy resources more rapidly on the OCS and promote U.S. energy independence. This rule would also significantly reduce costs to developers for expanding renewable energy development in an environmentally sound manner. Similarly, BLM plans to update its regulations for onshore rights-of-way, leasing, and operations related to all activities associated with renewable energy and transmission lines (1004–AE78). This proposed rule would improve permitting activities and processes to facilitate increased renewable energy production on public lands.

**Upholding Trust Responsibilities to Federally-Recognized American Indian and Alaska Native Tribes, Restoring Tribal Lands, and Protecting Natural and Cultural Resources**

Among the Department’s most important responsibilities is its commitment to honor the nation-to-nation relationship between the Federal Government and Tribes. Secretary Haaland is strongly committed to strengthening how the Department carries out its trust responsibilities and to increasing economic development opportunities for Tribes and other historically underserved communities. As part of these efforts, on April 27, 2021, Secretary Haaland signed SO 3400 entitled, “Delegation of Authority for Non-Gaming Off-Reservation Fee-to-Trust Acquisitions.” SO 3400 is intended to ensure that off-reservation fee-to-trust applications are effectively and efficiently processed. As Secretary Haaland noted upon signing the SO, “At Interior, we have an obligation to work with Tribes to protect their lands and ensure that each Tribe has a homeland where its citizens can live together and lead safe and fulfilling lives . . . . Our actions today will help us meet that obligation and help empower Tribes to determine how their lands are used—from conservation to economic development projects.”

To advance the Department’s trust responsibilities, the Bureau of Indian
Affairs (BIA) is currently identifying opportunities to promote Tribal economic growth and development. For example, BIA is working to remove barriers to the development of renewable energy and other resources in Indian country. During FY 2021, BIA finalized a rule that removed several required items from Tribal Energy Resource Agreement (TERA) applications and offered a new economic development option for Tribal Energy Development Organizations (TEDOs) (1076–AF65) (86 FR 40147, July 27, 2021).

In consultation with Tribes, BIA has been engaged in efforts to update and improve its regulations governing how it manages land held in trust or in restricted status for Tribes and individual Indians. This year, BIA published a final rule that modernizes the way the BIA Land Title and Records Office (LTRO) maintains title to Indian trust land and streamlines the process for probating estates that contain trust property to reduce delays (1076–AF56) (86 FR 55031, August 16, 2021). The bureau has also launched a broader review to determine whether any regulatory reforms are needed to facilitate restoration of Tribal lands and safeguard natural and cultural resources. The BIA has preliminarily identified as a candidate for revision the regulations governing leases of Indian land for agricultural purposes, which are found at 25 CFR part 162 (1076–AF66).

The BIA is also committed to improving regulations meant to protect sacred and cultural resources. The BIA is working with the National Park Service (NPS) to consult with Tribes on updates to regulations implementing the Native American Graves and Repatriation Act (NAGPRA), 43 CFR 10 (1024–AE19). These regulations would provide a systematic process for the disposition and repatriation of Native American human remains, funerary objects, sacred objects, and objects of cultural patrimony. The updates are intended to simplify and improve the regulatory process for repatriation, rectify provisions in the current regulations that inhibit and effectively prevent respectful repatriation, and remove the burden on Indian Tribes and Native Hawaiian organizations to initiate the process and add a requirement for museums and Federal agencies to complete the process.

Advancing Equity and Supporting Underserved Communities

The Biden-Harris administration and Secretary Haaland recognize and support the goals of advancing equity and addressing the needs of underserved communities. In January 2021, the President signed Executive Order 13985 entitled, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.” This Executive order directs all Federal agencies to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. In FY 2022, the Department will undertake a number of regulatory actions that will assist people who reside in underserved communities.

The BLM (1004–AE60), FWS (1018–BD78), and NPS (1024–AE75), are proposing right-of-way (ROW) rules that would improve efficiencies in the communications programs, including plans and agreements for electric transmission, distribution facilities and broadband facilities. These rules are intended to increase services, such as broadband connectivity, with resulting benefits to underserved communities and visitors to Departmental lands and promote good governance.

Investing in Healthy Lands, Waters and Local Economies and Strengthening Conservation, and Protecting Endangered Species and Their Habitat

The Department’s FY 2022 regulatory agenda will continue to advance the goals of investing in healthy lands, waters, and local economies across the country. These regulatory efforts, which are consistent with the Biden-Harris administration’s “America the Beautiful” Initiative, include expanding opportunities for outdoor recreation, including hunting and fishing, for all Americans; enhancing conservation stewardship; and improving the management of species and their habitat.

For example, the U.S. Fish and Wildlife Service (FWS), opened, for the first time, seven national wildlife refuges (NWRs), totaling 2.1 million acres of public lands, that were previously closed to hunting and sport fishing. Hunters and anglers are among the most ardent conservationists. The FWS opened or expanded hunting and sport fishing at 81 other NWRs and added pertinent station-specific regulations for migratory game bird hunting, upland game hunting, big game hunting, and sport fishing at this NFH for the 2021–2022 season. Finally, FWS made regulatory changes to existing station-specific regulations to reduce the regulatory burden on the public, increase access for hunters and anglers on FWS lands and waters, and comply with a Presidential mandate for plain language standards. By responding to comments from the public, the Department is enhancing the lives of millions of Americans, promoting conservation stewardship, and stimulating the national economy (86 FR 48822, August 31, 2021).

The NPS is also pursuing several regulatory actions under the Department’s direction and in accordance with these goals. These regulatory actions would authorize recreational activities, such as off-road vehicle use, snowmobiling, the use of motorized and non-motorized vessels, personal watercraft, and bicycling, within appropriate, designated areas of certain National Park System units. These regulations would benefit local economies as well as promote healthy lands and waters.

The Biden-Harris administration and Secretary Haaland are strongly committed to strengthening conservation and improving conservation partnerships. Through this regulatory plan, the Department affirms the importance of the Endangered Species Act (ESA) in providing a broad and flexible framework to facilitate conservation with a variety of stakeholders. The Department, through FWS, is committed to working with diverse Federal, Tribal, state, and industry partners to not only protect and recover America’s imperiled wildlife but to ensure the ESA is helping meet 21st century challenges.

In FY 2022, FWS will continue its reviews of several ESA rules that were finalized prior to January 20, 2021, to continue improving the implementation of the ESA so that it is clearly and consistently applied, helps recover listed species, and provides the maximum degree of certainty possible to all parties. For example, FWS and the National Marine Fisheries Service (NMFS) are reviewing the final rule that became effective on January 15, 2021, entitled, “Regulations for Listing Endangered and Threatened Species and Designating Critical Habitat,” that established a regulatory definition of “habitat.” FWS is also reviewing the final rule entitled, “Endangered and Threatened Wildlife Regulations for Designating Critical Habitat,” that became effective on
Bureau of Indian Affairs

The BIA enhances the quality of life, promotes economic opportunity, and protects and improves the trust assets of approximately 1.9 million American Indians, Indian Tribes, and Alaska Natives. The BIA maintains a government-to-government relationship with the 574 Federally-Recognized Indian Tribes. The BIA also administers and manages 55 million acres of surface land and 57 million acres of subsurface minerals held in trust by the United States for American Indians and Indian Tribes.

Regulatory and Deregulatory Actions

In FY 2021, BIA finalized a rule that removed several required items from TEDO applications and offers a new economic development option for TEDOs (86 FR 40147, July 27, 2021).

The BIA also published a final rule that modernizes the manner in which the BIA LTRO maintains title to Indian trust land and streamlines the process for adjudicating probates of estates containing trust property to reduce delays (86 FR 45631, August 16, 2021).

The BIA intends to prioritize the following rulemakings in FY 2022:

Tribal Transportation Program: Allowable Lengths of Access Roads (1076–AF48)

This rule would change the allowable length of access roads in the National Tribal Transportation Facilities Inventory, as determined by 25 CFR 170.247, to increase the 15-mile limits on the length of access roads and create parity among all Tribes, regardless of land base or remoteness of location.

Tribal Self-Governance PROGRESS Act Regulations (1076–AF62)

This rule would implement the requirements of the PROGRESS Act requiring updates to BIA’s regulations governing Tribal Self-Governance. The PROGRESS Act amends subchapter I of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5301 et seq., which addresses Indian Self-Determination, and subchapter IV of the ISDEAA which addresses the Department’s Tribal Self-Governance Program. The PROGRESS Act calls for a negotiated rulemaking committee to be established under 5 U.S.C. 563, with membership consisting only of representatives of Federal and Tribal governments, with the Office of Self-Governance serving as the lead agency for the Department. The PROGRESS Act also authorizes the Secretary to adapt negotiated rulemaking procedures to the unique context of self-governance and the government-to-government relationship between the United States and Indian Tribes.

Indian Business Incubators Program (1076–AF63)

This rule would establish the structure for the Office of Indian Energy and Economic Development (IEED) to implement the Native American Business Incubators Program, which was established by statute in October 2020. The rule will establish how IEED will provide competitive grants to eligible applicants to establish and operate business incubators that serve Tribal reservation communities. The business incubators will provide tailored business incubation services to Native businesses and Native entrepreneurs to overcome the unique obstacles they confront in offering products and services to reservation communities.

Agricultural Leasing of Indian Land (1076–AF66)

This rule would update provisions addressing leasing of trust or restricted land (Indian land) for agricultural purposes to reflect updates that have been made to business and residential leasing provisions and address outdated provisions.

Federal Recognition of Tribes Under Alaska IRA (1076–AF51)

This rule will establish criteria and procedures for groups seeking recognition as Tribes under the Alaska Indian Reorganization Act (Alaska IRA), which is separate and distinct from the Indian Reorganization Act of 1934, which has its own set of regulations for seeking recognition as Tribes. The Alaska IRA provides that groups of Indians in Alaska having a common bond of occupation, or association, or residence within a well-defined neighborhood, community, or rural district may organize to adopt constitutions and bylaws and receive charters of incorporation and Federal loans. This rule will also establish what documents are required to apply. To date, there has been no regulatory process or criteria established for seeking recognition under the Alaska IRA.

Elections of Osage Minerals Council (1076–AF58)

Current BIA regulations address how BIA conducts elections of offices of the Osage Tribe, including provisions addressing nominating conventions and
petitions, election notices, opening and closing of polls, ballots, and contesting elections. This rule will remove outdated and unnecessary provisions. Statutory changes and the Osage Nation Constitution have significantly pared down the role of BIA in the Tribe’s elections. The only remaining portion that will be included in this rule states that BIA will provide, at the Osage Nation’s request, a list of voters and their headright interests to the Osage Minerals Council Election Board.

Bureau of Indian Education

The Bureau of Indian Education (BIE) mission is to provide students at BIE-funded schools with a culturally relevant, high-quality education that prepares students with the knowledge, skills, and behaviors needed to flourish in the opportunities of tomorrow, become healthy and successful individuals, and lead their communities and sovereign nations to a thriving future that preserves their unique cultural identities. The BIE is the preeminent provider of culturally relevant educational services and supports provided by highly effective educators to students at BIE-funded schools to foster lifelong learning.

Regulatory and Deregulatory Actions

As BIE continues its work to fulfill its mission while keeping students and school staff safe and healthy, BIE finalized a new regulation in FY 2021 that will allow individual BIE-operated schools to retain the funding received through leasing their lands and facilities to third-parties, and direct that funding back into the school (86 FR 34943, July 1, 2021). The new regulation will also allow individual BIE-operated schools to retain fundraising proceeds and use those proceeds for the benefit of the school.

Appeals From Administrative Actions (1076–AF64)

This rule would clarify the processes for appeals of actions taken by officials in the Office of the Assistant Secretary Indian Affairs, BIA, BIE, and BTFA (collectively, Indian Affairs).

Bureau of Land Management

The BLM manages more than 245 million acres of public land, known as the National System of Public Lands, primarily located in 12 Western states, including Alaska. The BLM also administers 700 million acres of subsurface mineral estate throughout the Nation. The agency’s mission is to sustain the health, diversity, and productivity of America’s public lands for the use and enjoyment of present and future generations.

Regulatory and Deregulatory Actions

The BLM has identified the following priority rulemaking actions for FY 2022:

Livestock Grazing (1004–AE82)

This proposed rule would revise BLM’s grazing regulations to improve resource management and increase efficiency by streamlining and clarifying grazing processes and improving coordination among Federal, State, and local government entities. The proposed rule would revise the regulations at 43 CFR parts 4100, 1600, and 1500. These revisions and additions would help to provide the public and land managers with accurate and reliable information regarding grazing administration on public lands.


The BLM is proposing amendments to its existing ROW regulations to streamline and improve efficiencies in the communications uses program, update the cost recovery fee schedules for ROW work activities, and include provisions governing the development and approval of operating plans and agreements for ROWs for electric transmission and distribution facilities. Communications uses, such as broadband, are a subset of ROW activities authorized under the Federal Land Policy and Management Act of 1976 (FLPMA), as amended. Cost recovery fees apply to most ROW activities authorized under either FLPMA or the Mineral Leasing Act of 1920, as amended. This proposed rule would also implement vegetation management requirements included in the Consolidated Appropriations Act, 2018 (codified at 43 U.S.C. 1772) to address fire risk from and to power-line ROWs on public lands and national forests. The regulatory amendments would also codify legislated agency requirements regarding review and approval of utilities maintenance plans, liability limitations, and definitions of hazard trees and emergency conditions.

Bonding (1004–AE68)

This proposed rule would update the bonding procedures for ROWs on BLM-managed public land. The proposed rule would revise the bonding portion of the BLM’s ROW regulations to make them clearer and easier to understand, which would facilitate efficient bond calculations.


This proposed rule would revise BLM’s regulations for ROWs, leasing, and operations related to all activities associated with renewable energy and transmission lines. The Energy Act of 2020 and E.O. 14008 prioritize the Department’s need to improve permitting activities and processes to facilitate increased renewable energy production on public lands.

Waste Prevention, Production Subject to Royalties, and Resource Conservation 43 CFR Parts 3160 and 3170 (1004–AE79)

This proposed rule would update BLM’s regulations governing the waste of natural gas through venting, flaring, and leaks on onshore Federal and Indian oil and gas leases. The proposed rule would address the priorities associated with Executive Order 14008. In addition, in accordance with Executive Order 13990, this proposed rule would reduce methane emissions in the oil and gas sector and mitigate impacts of climate change.

Revision of Existing Regulations Pertaining to Fossil Fuel Leases and Leasing Process 43 CFR Parts 3100 and 3400 (1004–AE80)

This proposed rule would revise BLM’s fossil fuel regulations to update the fees, rents, royalties, and bonding requirements related to oil and gas leasing, development, and production. The proposed rule would also update BLM’s process for leasing to ensure the protection and proper stewardship of the public lands, including potential climate and other impacts associated with fossil fuel activities.

Revision of Existing Regulations Retaining to Leasing and Operations of Geothermal 43 CFR Part 3200 (1004–AE84)

This proposed rule would update and codify BLM’s Geothermal Resource Orders into regulation, including common geothermal standard practices, and inspection requirements and procedures.

Protection, Management, and Control of Wild Horses and Burros 43 CFR Part 4700 (1004–AE83)

This proposed rule would address wild horse and burro management challenges by adding regulatory tools that better reflect BLM’s current statutory authorities. For example, the existing regulations do not address certain management authorities that Congress has provided since 1986 to...
control wild horse and burro populations, such as the BLM’s authority to sell excess wild horses and burros. Updating the regulations would also facilitate management strategies and priorities that were not utilized when the regulations were originally promulgated, such as the application of fertility control vaccines, managing for nonreproducing herds, and feeding and caring for unsold and unadopted animals at off-range corrals and pastures. The proposed rule would also clarify ambiguities and management limitations in the existing regulations.

Bureau of Ocean Energy Management

The mission of BOEM is to manage development of U.S. OCS energy and mineral resources in an environmentally and economically responsible way. The BOEM is responsible for stewardship of U.S. OCS energy and mineral resources, as well as protecting the environment that the development of those resources may impact. The resources we manage belong to the American people and future generations of Americans; wise use of and fair return for these resources are foremost in our management efforts.

In accordance with its statutory mandate under OCSLA, BOEM is committed to implementing its dual mission of promoting the expeditious and orderly development of the Nation’s energy resources while simultaneously protecting the marine, human, and coastal environment of the OCS State submerged lands and the coastal communities. Consistent with the policy outlined by the administration in E.O. 14008, BOEM is reevaluating all of its programs related to the offshore development of energy and mineral resources offshore. The BOEM is working with the Department as a whole to review options for expanding renewable energy production while evaluating alternatives to better protect the lands, waters, and biodiversity of species located within the U.S. exclusive economic zone.

Regulatory and Deregulatory Actions

In FY 2022, the BOEM plans to prioritize the following rulemaking actions:

Renewable Energy Modernization Rule (1010–AE04)

The BOEM’s most important regulatory initiative is focused on expanding offshore wind energy’s role in strengthening U.S. energy security and independence, create jobs, provide benefits to local communities, and further develop the U.S. economy. The BOEM’s renewable energy program has matured over the past 10 years, a time in which BOEM has conducted numerous auctions and issued and managed multiple commercial leases. Based on this experience, BOEM has identified multiple opportunities to update its regulations to better facilitate the development of renewable energy resources and to promote U.S. energy independence.

The BOEM is proposing a rule that would update the existing renewable energy regulations to help facilitate the timely and responsible development of renewable energy resources on the OCS and promote U.S. energy independence. This proposed rule contains reforms identified by BOEM and recommended by industry, including proposals for incremental funding of decommissioning accounts; more flexible geophysical and geotechnical survey submission requirements; streamlined approval of meteorological buoys; revised project verification procedures; and greater clarity regarding safety requirements. This rule advances the administration’s energy policies in a safe and environmentally sound manner that provides a fair return to the American taxpayer while, at the same time, significantly reducing industry development.

Air Quality Rule (1010–AE09)

In accordance with the administration’s renewed commitment to ensure the robust protection for the lands, waters, and biodiversity of the United States, BOEM is reevaluating the entirety of its air quality regulatory program and will propose further enhancements. The BOEM and the Department are proposing a new offshore air quality rule to tighten pollution standards for offshore operations and require improved pollution control technology. The proposed rule would amend regulations for air quality measurement, evaluation, and control for offshore oil and gas operations. The goal of this new proposed rule would be to improve the ambient air quality of the coastal States and their corresponding State submerged lands by addressing a number of issues that were not addressed by BOEM’s prior final air quality rule. The BOEM expects to revisit a number of the topics that were originally reviewed in 2016.

Bureau of Safety and Environmental Enforcement

The Bureau of Safety and Environmental Enforcement’s (BSEE) mission is to promote safety, protect the environment, and conserve resources offshore through vigorous regulatory oversight and enforcement. The BSEE is the lead Federal agency charged with improving safety and ensuring environmental protection related to conventional and renewable energy activities on the U.S. OCS.

Regulatory and Deregulatory Actions

The BSEE has identified the following rulemaking priorities for FY 2022:

Oil-Spill Response Requirements for Facilities Located Seaward of the Coast Line Proposed Rule (1014–AA44)

The Oil Spill Response Requirements regulations in 30 CFR part 254 were last updated over 20 years ago (62 FR 13996, Mar. 25, 1997). This proposed rule would update the existing regulations in order to incorporate the latest advancements in spill response and preparedness policies and technologies, as well as lessons learned and recommendations from reports related to the Deepwater Horizon explosion and subsequent oil spill.

Revisions to Subpart J—Pipelines and Pipeline Rights-of-Way Proposed Rule (1014–AA45)

This proposed rule would revise specific provisions of the current Pipelines and Pipeline ROW regulations under 30 CFR 250 subpart J in order to bring those regulations up to date with current technology and state-of-the-art safety equipment and procedures, primarily through the incorporation of industry standards.

Outer Continental Shelf Lands Act; Operating in High-Pressure and/or High-Temperature (HPHT) Environments (1014–AA49)

Currently, BSEE has no regulations specific to high pressure and/or high temperature (HPHT) projects, requiring BSEE to issue multiple guidance documents clarifying the specific HPHT information prospective operators should submit to BSEE to support the Bureau’s programmatic reviews and approvals of such projects. This proposed rule would formally codify BSEE’s existing process for reviewing and approving projects in HPHT environments.

Oil and Gas and Sulfur Operations in the Outer Continental Shelf-Blowout Preventer Systems and Well Control Revisions (1014–AA52)

The BSEE is revising existing regulations for well control and blowout preventer systems.
The BOEM currently has authority over all renewable energy activities on the OCS under regulations at 30 CFR part 585. The BOEM and BSEE are in the process of amending the Department’s Manual chapters to transfer the safety, environmental enforcement, and compliance functions relevant to renewable energy activities from BOEM to BSEE. Consistent with that effort, BSEE and BOEM would amend their respective regulations to reflect the split of functions between the two Bureaus.

Office of the Chief Information Officer

The Office of the Chief Information Officer (OCIO) provides leadership to the Department and its Bureaus in all areas of information management and technology. To successfully serve the Department’s multiple missions, the OCIO applies modern Information Technology tools, approaches, systems, and products. Effective and innovative use of technology and information resources enables transparency and accessibility of information and services to the public.

For FY 2022, OCIO is working on these priority rules:

Network Security System of Records (1090–AB14)

This rule would revise the Department’s Privacy Act regulations at 43 CFR 2.254 to claim Privacy Act exemptions for certain records in the DOI–49, Network Security, system of records from one or more provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k), because of criminal, civil, and administrative law enforcement requirements.

Insider Threat Program System of Records (1090–AB15)

This rule would revise the Department’s Privacy Act regulations at 43 CFR 2.254 to claim Privacy Act exemptions for certain records in the DOI–50, Insider Threat Program, system of records from one or more provisions of the Privacy Act pursuant to 5 U.S.C. 552a(j) and (k), because of criminal, civil, and administrative law enforcement requirements.

Personnel Security Files System of Records (1090–AB16)

This rule would revise the Department’s Privacy Act regulations at 43 CFR 2.254 to claim Privacy Act exemptions for certain records in the DOI–45, Personnel Security Files, system of records from one or more provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k), because of criminal, civil, and administrative law enforcement requirements.

Social Security Number Fraud Prevention Act of 2017 Implementation (1090–AB24)

This direct final rule will amend 43 CFR part 2 to add subpart M to implement the Social Security Number Fraud Prevention Act of 2017, which directs Federal agencies to issue regulations that prohibit the inclusion of an individual’s Social Security number (SSN) on any document sent through the mail unless the Secretary deems it necessary. The regulations also include requirements for protecting documents with SSNs sent through postal mail.

Office of Environmental Policy and Compliance

The Office of Environmental Policy and Compliance (OEPC) serves as a leader in conservation stewardship and the sustainable development and use of Department-managed resources for the benefit of the public. The office fosters partnerships to enhance resource use and protection, as well as to expand public access to safe and clean lands under the Department’s jurisdiction. The office also strives to continually streamline environmental policies and procedures to increase management effectiveness and efficiency, reduce duplicative practices, and realize cost savings.

For FY 2022, OEPC will publish in the Federal Register:

Implementation of the National Environmental Policy Act (NEPA) of 1969 (1090–AB18)

This rule would develop regulations to streamline OEPC’s NEPA process and comply with E.O. 13990 and SO 3399.

Office of Grants Management

The Office of Grants Management is responsible for providing executive leadership, oversight, and policy for the financial assistance across the Department.

Financial Assistance Interior Regulation (1090–AB23)

This rule will align the Department’s regulations with new regulatory citations and requirements adopted by the Office of Management and Budget (OMB). On August 13, 2020, OMB published a revision to sections of Title 2 of the Code of Federal Regulations, Guidance for Grants and Agreements. The revision was an administrative simplification and did not make any substantive changes to 2 CFR part 200 policies and procedures. This rule will codify these changes in the Department’s financial assistance regulations located in 2 CFR part 1402.

Office of Hearings and Appeals

The Office of Hearings and Appeals (OHA) exercises the delegated authority of the Secretary to conduct hearings and decide appeals from decisions of the Bureaus and Offices of the Department. The OHA provides an impartial forum for parties who are affected by the decisions of the Department’s Bureaus and Offices to obtain independent review of those decisions. The OHA also handles the probating of Indian trust estates, ensuring that individual Indian interests in allotted lands, their proceeds, and other trust assets are conveyed to the decedents’ rightful heirs and beneficiaries.

Updates to American Indian Probate Regulations (1094–AA55)

This final rule will make regulatory changes relating to efficiency and streamlining of probate processes, ensuring that the Department meets its trust obligations, and helping achieve the American Indian Probate Reform Act statutory goal of reducing fractionalization of trust property interests.

Practices Before the Department of Interior (1094–AA56)

This direct final rule will amend existing regulations to keep up to date office addresses for hearings and appeals purposes, to allow for the OHA Director to issue interim orders in emergency circumstances, and to allow for the OHA Director to issue standing orders that will improve OHA’s service to the public and the parties by modernizing its processes.

Office of Natural Resources Revenue

The Office of Natural Resources Revenue (ONRR) continues to collect, account for, and disburse revenues from Federal offshore energy and mineral leases and from onshore mineral leases on Federal and Indian lands. The ONRR operates nationwide and is primarily responsible for the timely and accurate collection, distribution, and accounting of revenues associated with mineral and energy production.

ONRR 2020 Valuation Reform and Civil Penalty Rule: Final Withdrawal Rule (1012–AA27)

The ONRR is withdrawing the ONRR 2020 Valuation Reform and Civil

Amendments to ONRR’s Mail Addresses Listed in Title 30 CFR, Chapter XII (1012–AA28)

This rule will amend mailing addresses listed in parts of Title 30 CFR, Chapter XII due to ONRR’s main building renovation, which changed the organizations mailing addresses.

Civil Monetary Penalty Rates Inflation Adjustments for Calendar Year 2022 (1012–AA31)

This rule will adjust the maximum civil monetary penalty rates for inflation and announces the rates applicable to calendar year 2022.

Office of Small and Disadvantaged Business Utilization

The Office of Small and Disadvantaged Business Utilization advises the Secretary on small business issues and collaborates with leadership to maximize small business opportunities. The office implements policies, procedures, and training programs for the Department to emphasize its commitment to contracting with small businesses. The mission also includes outreach to small and disadvantaged business communities, including Indian economic enterprises, small disadvantaged, women-owned, veteran-owned, service-disabled veteran owned, small businesses located in historically underutilized business zones areas, and the Ability One Program.

Department of the Interior Acquisition Regulations, Buy Indian Act Acquisition Regulations (1090–AB21)

This rule would revise regulations implementing the Buy Indian Act, which provides the Department with authority to set aside procurement contracts for Indian-owned and controlled businesses. These revisions would eliminate barriers to Indian Economic Enterprises from competing on certain construction contracts, expand Indian Economic Enterprises’ ability to subcontract construction work consistent with other socio-economic set-aside programs, and give greater preference to Indian Economic Enterprises when a deviation from the Buy Indian Act is necessary, among other updates (86 FR 59338, October 27, 2021).

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement (OSMRE) was created by the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The OSMRE works with States and Tribes to ensure that citizens and the environment are protected during coal mining and that the land is restored to beneficial use when mining is finished. The OSMRE and its partners are also responsible for reclaiming and restoring lands and water degraded by mining operations before 1977. The OSMRE focuses on overseeing the state programs and developing new tools to help the states and tribes get the job done.

The OSMRE also works with colleges and universities and other State and Federal agencies to further the science of reclaiming mined lands and protecting the environment, including initiatives to promote planting more trees and establishing much-needed wildlife habitat.

Regulatory and Deregulatory Actions

The OSMRE does not currently expect to finalize any significant regulatory actions during FY 2022. The OSMRE does anticipate publishing:

Ten Day Notices (1029–AC81)

This rule would reexamine OSMRE’s regulations on the ten-day notices rule that went into effect on December 24, 2020.

Emergency Preparedness for Impoundments (1029–AC82)

This rule would incorporate certain aspects of the Federal Guidelines for Dam Safety (FGDS) into OSMRE’s existing regulations. These regulations relate to emergency preparedness for impoundments and propose to incorporate the FGDS Emergency Action Plans (EAP) and After-Action Reports (AAR). The proposed rule may result in revisions to OSMRE’s regulations at 30 CFR 701.5, 780.25, 784.16, 816.49, 817.49, 816.84, and 817.84. Also, OSMRE may add new provisions to the regulations to explain the EAP and AAR requirements and align the classification of impoundments with industry and other Government agency standards.

U.S. Fish and Wildlife Service

The mission of FWS is to work with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people. The FWS also provides opportunities for Americans to enjoy the outdoors and our shared natural heritage. The FWS also promotes and encourages the pursuit of recreational activities such as hunting and fishing and wildlife observation. The FWS manages a network of 567 NWRs, with at least one refuge in each U.S. State and territory, and with more than 100 refuges close to major urban centers. The Refuge System plays an essential role in providing outdoor recreation opportunities to the American public. In 2019, more than 59 million visitors went to refuges to hunt, fish, observe or photograph wildlife, or participate in environmental education or interpretation.

The FWS fulfills its responsibilities through a diverse array of programs that:

• Protect and recover endangered and threatened species;
• Monitor and manage migratory birds;
• Restore nationally significant fisheries;
• Enforce Federal wildlife laws and regulate international trade;
• Conserve and restore wildlife habitat such as wetlands;
• Manage and distribute over a billion dollars each year to States, territories, and Tribes for fish and wildlife conservation;
• Help foreign governments conserve wildlife through international conservation efforts; and
• Fulfill our Federal Tribal trust responsibility.

Regulatory and Deregulatory Actions

The FWS has identified the following priority rulemaking actions for FY 2022:

Regulations Under the Endangered Species Act (ESA):

The FWS will promulgate multiple regulatory actions under the ESA to prevent the extinction of and facilitate the recovery of both domestic and foreign animal and plant species. Accordingly, FWS will add species to, remove species from, and reclassify species on the Lists of Endangered and Threatened Wildlife and Plants and designate critical habitat for certain listed species, in accordance with the National Listing Workplan. The Workplan enables FWS to prioritize workloads based on the needs of candidate and petitioned species, while providing greater clarity and predictability about the timing of listing determinations to State wildlife agencies, nonprofit organizations, and other stakeholders and partners. The Workplan represents the conservation priorities of FWS based on its review of scientific information. The goal is to encourage proactive conservation so that Federal protections are not needed in the first place. The FWS also plans to promulgate several species-specific rules to protect threatened species under section 4(d) of the ESA.
The Unified Agenda includes rulemaking actions pertaining to these issues:

Endangered and Threatened Wildlife and Plants; Revised Designation of Critical Habitat for the Northern Spotted Owl (1018–BF01)

This rule revised the designated critical habitat for the northern spotted owl (Strix occidentalis caurina) under the ESA. After a review of the best available scientific and commercial information, FWS withdrew the January 15, 2021, final rule that would have excluded approximately 3.4 million acres of designated critical habitat for the northern spotted owl. Instead, FWS revised the species’ designated critical habitat by excluding approximately 204,294 acres (82,675 hectares) in Benton, Clackamas, Coos, Curry, Douglas, Jackson, Josephine, Klamath, Lane, Lincoln, Multnomah, Polk, Tillamook, Washington, and Yamhill Counties, Oregon, under section 4(b)(2) of the Act (86 FR 62606, November 10, 2021).

Endangered and Threatened Wildlife and Plants; Listing Determination and Critical Habitat Designation for the Monarch Butterfly (1018–BE30)

This rule would list the monarch butterfly under the ESA in FY 2024, if listing is still warranted at that time. FWS would also propose to designate critical habitat for the species, if prudent and determinable.

Endangered and Threatened Wildlife and Plants; Revision of the Regulations for Listing Endangered and Threatened Species and Designation of Critical Habitat (1018–BE60)

The FWS and the National Marine Fisheries Service propose to rescind the final rule titled “Regulations for Listing Endangered and Threatened Species and Designating Critical Habitat” that was published on December 16, 2020, and became effective on January 15, 2021. The proposed rescission, if finalized, would remove the regulations established by that rule.

Endangered and Threatened Wildlife and Plants; Regulations for Listing Endangered and Threatened Species and Designating Critical Habitat (1018–BF95)

This joint Department of the Interior and the Department of Commerce rule would review the previous rulemaking action with the title “Endangered and Threatened Wildlife and Plants; Regulations for Listing Species and Designating Critical Habitat,” (84 FR 45020; August 27, 2019), in which we revised the regulations for adding and removing species from the Lists of Endangered and Threatened Wildlife and Plants and clarified procedures for designation of critical habitat. The Department’s review will determine whether and how that rule should be revised.

Endangered and Threatened Wildlife and Plants; Revisiting the Interagency Cooperation Final Rule (1018–BF96)

This joint rule by the Departments of Commerce and the Interior would review Endangered and Threatened Wildlife and Plants; Regulations for Interagency Cooperation (84 FR 44976; August 27, 2019) to determine whether and how that rule should be rescinded.

Endangered and Threatened Wildlife and Plants; Compensatory Mitigation Mechanisms Under the Endangered Species Act (1018–BF63):

This rulemaking action would address section 329 of the National Defense Authorization Act for Fiscal Year 2021, Objectives, Performance Standards, and Criteria for Use of Wildlife Conservation Banking Programs. This law requires FWS to publish an advance notice of proposed rulemaking (ANPRM) by January 1, 2022. The purpose of the ANPRM is to inform FWS’s development of regulations related to wildlife conservation banking to ensure opportunities for Department of Defense participation in wildlife conservation banking programs pursuant to section 2694c of title 10, United States Code.

Regulations Governing Take of Migratory Birds (1018–BD76):

On January 7, 2021, the FWS published a final rule defining the scope of the Migratory Bird Treaty Act (MBTA) as it applies to conduct resulting in the injury or death of migratory birds protected by the MBTA. We are now revoking that rule. The effect of this rule is a return to implementing the MBTA as prohibiting incidental take and applying enforcement discretion, consistent with judicial precedent.

Protection of Migratory Birds; Definitions and Authorizations (1018–BF71)

This rule would amend FWS regulations by providing definitions to terms used in the MBTA. This proposed rule would clarify that the MBTA’s prohibitions on taking and killing migratory birds includes foreseeable, direct taking and killing that is incidental to other activities. The rule would also propose to establish authorizations for compliance with MBTA prohibitions.

Eagle Permits; Incidental Take (1018–BE70)

This rule would provide potential approaches for further expediting and simplifying the permit process authorizing incidental take of eagles. The new process would improve and make more efficient the permitting process for incidental take of eagles in a manner that is compatible with the preservation of bald and golden eagles.

Possession of Eagle Specimens for Religious Purposes (1018–BB88)

This rule would propose extending legal access to bald and golden eagle parts and feathers for religious use to persons other than enrolled members of federally recognized Tribes.

2021–2022 Station-Specific Hunting and Sport Fishing Regulations (1018–BF09)

The FWS opens, for the first time, seven National Wildlife Refuges (NWRs) that are currently closed to hunting and sport fishing. In addition, the Service opens or expands hunting and sport fishing at 81 other NWRs and adds pertinent station-specific regulations for other NWRs that pertain to migratory game bird hunting, upland game hunting, big game hunting, and sport fishing for the 2021–2022 season. The Service also opens hunting or sport fishing on one unit of the National Fish Hatchery System (NFH). We add pertinent station-specific regulations that pertain to migratory game bird hunting, upland game hunting, big game hunting, and sport fishing at this NFH for the 2021–2022 season. Finally, we make regulatory changes to existing station-specific regulations in order to reduce the regulatory burden on the public, increase access for hunters and anglers on Service lands and waters, and comply with a Presidential mandate for plain language standards (86 FR 48822, August 31, 2021).
Revision of Regulations Implementing the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); Updates Following the Eighteenth Meeting of the Conference of the Parties (CoP18) to CITES (1018–BF14)

The FWS is taking direct final action to revise regulations that implement the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES or Treaty) by incorporating certain non-controversial provisions adopted at the sixteenth through eighteenth meetings of the Conference of the Parties (CoP16–CoP18) to CITES and clarifying and updating certain other provisions. These changes will bring U.S. regulations in line with certain revisions adopted at the three most recent meetings of the CoP, which took place in March 2013 (CoP16), September–October 2016 (CoP17), and August 2019 (CoP18). The revised regulations will help FWS more effectively promote species conservation, help us continue to fulfill our responsibilities under the Treaty, and help those affected by CITES to understand how to conduct lawful international trade.

National Park Service

The National Park Service (NPS) preserves the natural and cultural resources and values within 423 units of the National Park System encompassing more than 85 million acres of lands and waters for the enjoyment, education, and inspiration of this and future generations. The NPS also cooperates with partners to extend the benefits of resource conservation and outdoor recreation throughout the United States and the world.

Regulatory and Deregulatory Actions

The following are the NPS’s rulemaking priorities during FY 2022 year:

Native American Graves Protection and Repatriation Act Regulations (1024–AE19)

This rule would revise the NAGPRA implementing regulations. The rule would eliminate ambiguities, correct inaccuracies, simplify excessively burdensome and complicated requirements, clarify timelines, and remove offensive terminology in the existing regulations that have inhibited the respectful repatriation of most Native American human remains. This rule would simplify and improve the regulatory process for repatriation and thereby advance the goals of racial justice, equity, and inclusion.

Colonial National Historical Park: Vessels and Commercial Passenger-Carrying Motor Vehicles (1024–AE39)

This final rule will amend the special regulations for Colonial National Historical Park. This rule will remove a regulation that prevents the Superintendent from designating sites within the park for launching and landing private vessels. The rule will also remove outdated permit and fee requirements for commercial passenger-carrying vehicles.

Visitor Experience Improvements Authority Contracts (1024–AE47)

This proposed rule would implement the Visitor Experience Improvements Authority (VEIA) given to NPS by Congress in title VII of the National Park Service Centennial Act. This authority allows the NPS to award and administer commercial services contracts for the operation and expansion of commercial visitor facilities and visitor services programs in units of the National Park System. The VEIA supplements but does not replace the existing authority granted to the NPS in the Concessions Management Improvement Act of 1998 to enter into concession contracts.

Whiskeytown National Recreation Area: Bicycling (1024–AE52)

This rule would allow bicycles on approximately 75 miles of trails throughout Whiskeytown National Recreation Area; 17 miles of trail will be newly constructed. Bicycling is an established use at the recreation area that has never been properly authorized under NPS bicycle regulations.

Pictured Rocks National Lakeshore: Snowmobiles (1024–AE53)

This final rule will clarify where snowmobiles may be used within the boundaries of the Lakeshore by replacing general language allowing snowmobiles on unplowed roads and the shoulders of plowed roads with a comprehensive list of designated snowmobile routes.

Gulf Islands National Seashore: Watercraft (1024–AE55)

This final rule will amend special regulations for Gulf Island National Seashore that govern the use of personal watercraft (PWC) within the National Seashore in Mississippi and Florida. NPS regulations only allow for the operation of PWCs in park areas were authorized by special regulation.

Commercial Visitor Services; Concession Contracts (1024–AE57)

This final rule will revise regulations that govern the solicitation, award, and administration of concessions contracts to provide commercial visitor services at National Park System units under the Concessions Management Improvement Act of 1998. This rule would reduce administrative burdens and expand sustainable, high quality, and contemporary concessioner-provided visitor services in national parks.

Curation of Federally-Owned and Administered Archeological Collections (1024–AE58)

This final rule will amend the regulations for the curation of federally-owned and administered archeological collections to establish definitions, standards, and procedures to dispose of particular material remains that are determined to be of insufficient archaeological interest. This rule will promote more efficient and effective curation of these archeological collections.

Ozark National Scenic Riverways; Motorized Vessels (1024–AE62)

This rule would amend special regulations for Ozark National Scenic Riverways. The rule would modify regulations governing the use of motorized vessels within the Riverways to help accommodate a variety of desired river conditions and recreational uses, promote high quality visitor experiences, promote visitor safety, and minimize conflicts among different user groups. The rule would implement a management action that represents a compromise between user groups and was the result of a long planning process with robust community engagement.

Mount Rainier National Park; Fishing (1024–AE66)

This rule would revise special regulations for Mount Rainier National Park to remove all fishing closures and restrictions from 36 CFR 7.5. Instead, the NPS would manage fishing through administrative orders in the Superintendent’s Compendium. This action would help implement a 2018 Fish Management Plan that aims to conserve native fish populations and restore aquatic ecosystems by reducing or eliminating nonnative fish.

Bureau of Reclamation

The Bureau of Reclamation’s Reclamation mission is to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. To accomplish this mission, Reclamation employs management, engineering, and...
science to achieve effective and environmentally sensitive solutions.

Reclamation’s projects provide:
Irrigation water service; municipal and industrial water supply; hydroelectric power generation; water quality improvement; groundwater management; fish and wildlife enhancement; outdoor recreation; flood control; navigation; river regulation and control; system optimization; and related uses. In addition, Reclamation continues to provide increased security at its facilities.

Regulatory and Deregulatory Actions

Reclamation’s rulemaking priorities for FY 2022 include the following:
Public Conduct on Bureau of Reclamation Facilities, Lands and Waterbodies (1006–AA58)

This proposed update to an existing rule would revise existing definitions for the use of aircraft, the possession of firearms, camping, swimming, and winter recreation for the wide range of circumstances found across Reclamation and would clarify the permitting of memorials and correct inconsistencies found within this part.

Departmental

For FY 2022, the Department intends to publish in the Federal Register:
Paleontological Resources Preservation. (1093–AA25)

This rule addresses the management, collection, and curation of paleontological resources on or from Federal lands administered by the Department using scientific principles and expertise, including collection in accordance with permits; curation in an approved repository; and maintenance of confidentiality of specific locality data.

DEPARTMENT OF JUSTICE (DOJ)—FALL 2021

Statement of Regulatory Priorities

The mission of the Department of Justice is to uphold the rule of law, to protect the public against foreign and domestic threats, to provide Federal leadership in preventing and controlling crime, and to ensure equal justice under the law for all. In carrying out this mission, the Department is guided by the core values of integrity, fairness, and commitment to promoting the impartial administration of justice—including for those in historically underserved, vulnerable, or marginalized communities. Consistent with its mission and values, the Department is prioritizing activities that strengthen enforcement of civil rights laws, defend against domestic and international terrorism, combat gun violence, and reform criminal justice systems. Because the Department of Justice is primarily a law enforcement agency, not a regulatory agency, it carries out its principal investigative, prosecutorial, and other enforcement activities through means other than the regulatory process.

The regulatory priorities of the Department include initiatives in the areas of immigration, criminal justice reform, and gun violence reduction. Those initiatives, as well as regulatory initiatives by several other components carrying out key law enforcement priorities, are summarized below.

Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)

ATF issues regulations to enforce the Federal laws relating to the manufacture, importation, sale, and other commerce in firearms and explosives. ATF’s mission and regulations are designed to, among other objectives: (1) Curb illegal traffic in, and criminal use of, firearms and explosives; and (2) assist State, local, and other Federal law enforcement agencies in reducing violent crime. ATF will continue, as a priority during fiscal year 2021, to seek modifications to its regulations governing commerce in firearms and explosives in furtherance of these important goals.

ATF plans to finalize regulations regarding definitions of firearm, firearm frame or receiver, gunsmith, complete weapon, complete muffler or silencer device, privately made firearm, and readily, and finalize regulations on marking and recordkeeping that are necessary to implement these new or amended definitions (RIN 1140–AA54). The intent of this rulemaking is to consider technological developments and modern terminology in the firearms industry, and to enhance public safety by helping to stem the proliferation of unmarked, privately made firearms that have increasingly been recovered at crime scenes. Further, ATF plans to finalize regulations to implement certain provisions of Public Law 105–277, Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (RIN 1140–AA10), and to set forth factors considered when evaluating firearms with an attached stabilizing brace to determine whether they are considered firearms under the National Firearms Act and/or the Gun Control Act (RIN 1140–AA55). This second rule would make clear that all weapons that fall under the National Firearms Act, however they are made, are subject to its heightened regulations—including registration and background check requirements. ATF also has begun a rulemaking process that amends 27 CFR part 447 to update the terminology in ATF’s import control regulations based on similar terminology amendments made by the Department of State on the U.S. Munitions List in the International Traffic in Arms Regulations, and the Department of Commerce on the Commerce Control List in the Export Administration Regulations (RIN 1140–AA49).

Bureau of Prisons (BOP)

BOP issues regulations to enforce the Federal laws relating to its mission: To protect public safety by ensuring that federal offenders serve their sentences of imprisonment in facilities that are safe, humane, cost-efficient, and appropriately secure, and to provide reentry programming to ensure their successful return to the community.

Over the past year, the Bureau has successfully implemented its Incident Action Plan, developed in response to 2020 pandemic conditions to facilitate continuity of operations, supplies, inmate movement, visitation, staff training, and official staff travel. As pandemic conditions continue to evolve, BOP plans to continue to employ and improve its Incident Action Plan, currently comprised of BOP’s approved Pandemic Influenza Plan; its Incident Command System (ICS) framework; and guidance and directives from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), the Office of Personnel Management (OPM), DOJ, and the Office of the Vice President.

In the near future, BOP plans to finalize procedures for eligible inmates to earn FSA Time Credits, as authorized by the First Step Act of 2018 (FSA), Public Law 115–391, 132 Stat. 5194 (2018). The FSA provides that eligible inmates earn FSA Time Credits towards prerelease custody or early transfer to supervised release for successfully completing approved Evidence-Based Recidivism Reduction (EBRR) Programs or Productive Activities (PAs) assigned to each inmate based on the inmate’s risk and needs assessment.

BOP will also finalize regulations implementing additional legislative changes enacted in the FSA to broaden the Good Conduct Time Credit system, revise inmate disciplinary regulations, and provide effective literacy programming which serves both general and specialized inmate needs.
Civil Rights Division (CRT)

CRT works to uphold the civil and constitutional rights of all Americans, particularly some of the most vulnerable members of our society. Consistent with this mission, CRT plans to engage in three separate rulemakings under the Americans with Disabilities Act (ADA).

First, CRT plans to amend its current regulations under section 504 of the Rehabilitation Act of 1973, which prohibits discrimination based on disability in programs and activities conducted by an Executive agency, to bring them up to date. Second, the Department plans to publish a new ANPRM seeking public input on possible revisions to its ADA regulations to ensure the accessibility of equipment and furniture in public entities and public accommodations programs and services. Third, the Department of Justice intends to propose requirements for the construction and alteration of pedestrian facilities covered by subtitle A of title II of the ADA that are consistent with the Access Board’s minimum “Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way.” These requirements would ensure that sidewalks and other pedestrian facilities in the public right-of-way are accessible to and usable by individuals with disabilities.

Drug Enforcement Administration (DEA)

DEA is the primary agency responsible for coordinating the drug law enforcement activities of the United States and assists in the implementation of the President’s National Drug Control Strategy. DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended, collectively referred to as the Controlled Substances Act (CSA). DEA’s mission is to enforce the CSA and its regulations and bring to the criminal and civil justice system those organizations and individuals involved in the growing, manufacture, or distribution of controlled substances and listed chemicals appearing in or destined for illicit traffic in the United States. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States.

Pursuant to its statutory authority, DEA intends to propose a regulation that allows practitioners, subject to certain limitations, to supply up to a three-day supply of buprenorphine or other medications for maintenance and detoxification treatment of opioid use disorder, as instructed by Congress in Public Law 116–215 (RIN–1117–AB73). The intent of this rulemaking is to ensure patients with opioid use disorder have access to needed medications while longer-term treatment is being coordinated. DEA also anticipates finalizing a rulemaking action clarifying the procedures a registrant must follow in the event a suspicious order for controlled substances is received (RIN 1117–AB47).

Executive Office for Immigration Review (EOIR)

EOIR’s primary mission is to adjudicate immigration cases by fairly, expeditiously, and uniformly interpreting and administering the Nation’s immigration laws. Under delegated authority from the Attorney General, EOIR conducts immigration court proceedings, appellate reviews, and administrative hearings. Immigration judges in EOIR’s Office of the Chief Immigration Judge adjudicate cases to determine whether noncitizens should be ordered removed from the United States or should be granted some form of protection or relief from removal. The Board of Immigration Appeals (BIA) has jurisdiction over appeals from the decisions of immigration judges, as well as other matters. Accordingly, the Department of Justice has a significant role in the administration of the Nation’s immigration laws. The Attorney General also is responsible for civil litigation and criminal prosecutions related to the immigration laws.

Consistent with Executive Order 14010, EOIR is developing numerous regulations related to the asylum system. Specifically, EOIR is working with the Department of Homeland Security (DHS) to finalize a recently proposed rule to amend the procedures for the processing of asylum claims in expedited removal proceedings (RIN 1125–AB20). In addition, EOIR and DHS intend to propose a rule to address the circumstances in which an individual would be considered a member of a “particular social group” (RIN 1125–AB13). Similarly, EOIR and DHS intend to propose a rule to rescind bars to asylum implemented by three prior rules: RIN 1125–AA87 related to an applicant’s criminal activity, RIN 1125–AA91 related to an applicant’s transit through the United States, and RIN 1125–AB08 related to public health concerns. Moreover, EOIR intends to issue a rule to rescind or revise previous regulatory amendments regarding the time allowed for filing applications for asylum and withholding of removal by individuals in proceedings before EOIR (RIN 1125–AB15). EOIR is developing a proposed rule that would require immigration judges to conduct a hearing in which the applicant may provide testimony on his or her application for asylum and withholding of removal before the judge could deny the application (RIN 1125–AB22).

Finally, EOIR is also working to revise and update the regulations relating to immigration proceedings to increase efficiencies and productivity, while also safeguarding due process. EOIR is in the process of publishing a final rule regarding its new EOIR Case and Appeals System, which provides for greatly expanded electronic filing and calendaring for cases before EOIR’s immigration courts and the BIA (RIN 1125–AA81). In addition, EOIR is drafting a proposed rule that would codify administrative closure procedures before the immigration courts and the BIA and make other revisions to ensure that BIA adjudications appropriately balance due process and efficiency considerations (RIN 1125–AB18). Further, EOIR is planning to finalize a rule that would establish procedures for practitioners to provide individual document assistance without triggering the full obligations required of practitioners engaging in full representation of a noncitizen in EOIR proceedings (RIN 1125–AA83).

Federal Bureau of Investigation (FBI)

The Federal Bureau of Investigation is responsible for protecting and defending the United States against terrorist and foreign intelligence threats, upholding and enforcing the criminal laws of the United States, and providing leadership and criminal justice services to Federal, State, municipal, and international agencies and partners. Only in limited contexts does the FBI rely on rulemaking. For example, the FBI is currently drafting a rule that establishes the criteria for use by a designated entity in deciding fitness as described under the Child Protection Improvements Act (CPIA), 34 U.S.C. 40102, Public Law 115–141, div. S. title I, section 101(a)(1), Mar. 23, 2018, 132 Stat. 1123.

The CPIA requires that the Attorney General shall, by rule, establish the criteria for use by designated entities in making a determination of fitness described in subsection (b)(4) of the Act concerning whether an individual has been convicted of, or is under pending indictment for, a crime that bears upon
the provider’s responsibility to have
responsibility for the safety and
responsibility of children, the elderly, or
individuals with disabilities and shall
convey that determination to the
qualified entity. Such criteria shall be
based on the criteria established
pursuant to section 108(a)(3)(G)(i) of the
Prosecutorial Remedies and Other Tools
to end the Exploitation of Children
note) and section 658H of the Child Care
and Development Block Grant Act of

Office of Justice Programs (OJP)

OJP provides innovative leadership to
Federal, State, local, and tribal justice
systems by disseminating state-of-the-art
knowledge and practices and providing
financial assistance for the
implementation of crime fighting
strategies.

OJP published a notice of proposed
rulemaking for the Office of Juvenile
Justice and Delinquency Prevention
(OJJDP) Formula Grant Program on
August 8, 2016, and in early 2017
published a final rule addressing some
of those provisions. For other provisions
included in the proposed rule, OJJDP
received many comments that require
additional time for OJJDP to consider.
OJP published an additional final rule
removing certain provisions of the
regulations that are no longer legally
supported, and to make technical
corrections, in June 2021. OJJDP now
plans to publish a second notice of
proposed rulemaking addressing
amendments to the Juvenile Justice and
Delinquency Prevention Act included in
the Juvenile Justice Reform Act signed
into law on December 21, 2018, and the
remaining changes that OJJDP intends
to make to the formula grant program
regulation.

DOJ—CIVIL RIGHTS DIVISION (CRT)

Prerule Stage

101. • Nondiscrimination on the Basis of
Disability by State and Local
Governments and Places of Public
Accommodation; Equipment and
Furniture

Priority: Other Significant.
Legal Authority: 42 U.S.C. 12101 et
seq.

CFR Citation: 28 CFR 35; 28 CFR 36.
Legal Deadline: None.

Abstract: The ADA requires State and
local governments and public
accommodations to provide programs,
activities, and services in a manner that
is accessible to people with disabilities,
including non-fixed equipment and
furniture that is used in the delivery of
programs, activities, and services. The
ADA also requires that covered entities
communicate effectively with people
with disabilities and provide
appropriate auxiliary aids and services.

While some types of fixed equipment
and furniture are explicitly covered by
the 2010 Standards for Accessible
Design, there are no specific provisions
in the ADA regulations that include
standards for the accessibility of
equipment and furniture that are not
fixed. See, e.g., 28 CFR 36.406(b) (the
1991 and 2010 Standards apply to fixed
or built-in elements of buildings and
structures). Because the 2010 ADA
Standards include accessibility
requirements for some types of fixed
equipment (e.g., ATMs, washing
machines, dryers, tables, benches, and
vending machines), the Department
plans to look to these standards for
guidance, where applicable, when it
proposes accessibility standards for
equipment and furniture that is not
fixed.

The Department plans to publish an
ANPRM seeking public input on
possible revisions to its ADA
regulations to ensure the accessibility of
equipment and furniture in public
entities’ and public accommodations’
programs and services.

Statement of Need: The Department’s
Americans with Disabilities Act (ADA)
regulations contain the ADA Standards
for Accessible Design (the ADA
Standards) which provide accessibility
standards for some types of fixed or
built-in equipment and furniture.
However, there are no specific
provisions in the ADA Standards or the
ADA regulations governing the
accessibility of equipment and furniture
that are not fixed or built in. Changes
in technology have resulted in the
development and improved availability
of accessible equipment and furniture
that benefit individuals with disabilities,
and accessible equipment and furniture
is often critical to an entity’s ability to
provide an individual with a disability
equal access to its services. This rule is
necessary to ensure that inaccessible
equipment and furniture do not prevent
people with disabilities from accessing
State and local governments and public
accommodations’ programs and
services.

Summary of Legal Basis: The
summary of the legal basis for this
regulation is set forth in the above
abstract.

Alternatives: There are no appropriate
alternatives to issuing this ANPRM. The
Architectural and Transportation
Barriers Compliance Board (Access
Board) may issue minimum standards
on equipment and furniture, but these
standards only become binding when the
Department adopts the Access
Board’s standards through a rulemaking.
Alternatively, the Department may
create its own technical standards and
implement them through a rulemaking.

Anticipated Cost and Benefits: The
Department anticipates costs to covered
entities, including State and local
governments and places of public
accommodation. Entities may need to
acquire new equipment or furniture or
retrofit existing equipment and furniture
to meet technical standards that the
Department includes in its regulations.

Risks: Failure to implement technical
standards to ensure that people with
disabilities have access to equipment
and furniture in public entities’
and public accommodations’ programs and
services will make some of these
programs and services inaccessible to
people with disabilities.

Timetable:

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Regulatory Flexibility Analysis
Required: Undetermined.

Small Entities Affected: Businesses,
Governmental Jurisdictions,
Organizations.

Governmental Levels Affected: Local,
State.

Federalism: Undetermined.

Agency Contact: Rebecca Bond, Chief,
Disability Rights Section, Department
of Justice, Civil Rights Division, 4
Constitution Square, 150 M Street NE,
Washington, DC 20002, Phone: 202 305–
2952.

RIN: 1190–AA76

DOJ—CRT

Proposed Rule Stage

102. Implementation of the ADA
Amendments Act of 2008: Federally
Conducted (Section 504 of the
Rehabilitation Act of 1973)

Priority: Other Significant.
Legal Authority: Pub. L. 110–325; 29
U.S.C. 794 (sec. 504 of the Rehab. Act
of 1973); E.O. 12250 (45 FR 72855)

CFR Citation: 28 CFR 39.
Legal Deadline: None.

Abstract: Section 504 of the
Rehabilitation Act of 1973, as amended
(29 U.S.C. 794), prohibits discrimination
on the basis of disability in programs
and activities conducted by an
Executive agency. The Department
plans to revise its 504 Federally
conducted regulation at 28 CFR part 39
to incorporate amendments to the statute, including the changes in the meaning and interpretation of the applicable definition of disability required by the ADA Amendments Act of 2008, Public Law 110–325, 122 Stat. 3553 (Sep. 25, 2008); incorporate requirements and defenses stemming from judicial decisions; and make other non-substantive clarifying edits, including updating outdated terminology and references.

Statement of Need: This rule is necessary to bring the Department’s prior section 504 Federally conducted regulation, which has not been updated in three decades, into compliance with judicial decisions establishing rights and defenses under section 504, as well as statutory amendments to the Rehabilitation Act, including the new definition of disability provided by the ADA Amendments Act of 2008, which became effective on January 1, 2009. Additionally, following the passage of the Americans with Disabilities Act (ADA), amendments to the Rehabilitation Act sought to ensure that the same precepts and values embodied in the ADA were also reflected in the Rehabilitation Act. To ensure the intended parity between the two laws, it is also necessary to update the Federally conducted regulation to align it with the relevant provisions of Title II of the ADA. An updated Federally conducted regulation would consolidate the existing Section 504 requirements in one place for easy reference.

Summary of Legal Basis: The summary of the legal basis of authority for this regulation is set forth above in the abstract.

Alternatives: There are no appropriate alternatives to issuing this NPRM since it implements requirements and defenses arising from the statute and judicial decisions.

Anticipated Cost and Benefits:
Because the NPRM would incorporate existing legal requirements and defenses in the Department’s section 504 Federally conducted regulation, the Department does not anticipate any costs from this rule.

Risks: Failure to update the Department’s section 504 Federally conducted regulation to conform to legal requirements and defenses provided under statute and judicial decisions will interfere with the Department’s ability to meet its non-discrimination requirements under section 504.

Timetable:

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Additional Information: Transferred from RIN 1190–A960.
Agency Contact: Rebecca Bond, Chief, Disability Rights Section, Department of Justice, Civil Rights Division, 4 Constitution Square, 150 M Street NE, Washington, DC 20002, Phone: 202 305–2952.

DOJ—CRT

103. • Nondiscrimination on the Basis of Disability by State and Local Governments; Public Right-of-Way


Legal Authority: 42 U.S.C. 12134(a);
42 U.S.C. 12134(c)

CFR Citation: 28 CFR 35.
Legal Deadline: None.

Abstract: The Department of Justice anticipates issuing a Notice of Proposed Rulemaking that would establish accessibility requirements to ensure that sidewalks and other pedestrian facilities in the public right-of-way are accessible to and usable by individuals with disabilities.

The Americans with Disabilities Act (ADA) directs the Department of Justice to issue minimum guidelines to ensure that buildings, facilities, rail passenger cars, and vehicles are accessible, in terms of architecture and design, transportation, and communication, to individuals with disabilities. The Access Board intends to issue minimum accessibility guidelines for pedestrian facilities in the public right-of-way, called the Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way.

The ADA directs the Department of Justice to promulgate regulations implementing subtitle A of title II of the ADA. The ADA further directs that the Department of Justice’s regulations include standards that are consistent with the minimum ADA guidelines issued by the Access Board. Accordingly, the Department of Justice intends to propose requirements for the construction and alteration of pedestrian facilities covered by subtitle A of title II of the ADA that are consistent with the Access Board’s minimum Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way.

Statement of Need: This rule is necessary to ensure that pedestrian facilities in the public right-of-way are accessible to and usable by individuals with disabilities. The Access Board is required to issue minimum accessibility guidelines for pedestrian facilities in the public right-of-way, and the ADA requires the Department of Justice to include standards in its regulations implementing subtitle A of title II of the ADA that are consistent with the minimum ADA guidelines issued by the Access Board. Accordingly, the Department of Justice intends to propose requirements for the construction and alteration of pedestrian facilities covered by subtitle A of title II of the ADA that are consistent with the Access Board’s minimum Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way.

Summary of Legal Basis: The summary of the legal basis for this regulation is set forth in the above abstract.

Alternatives: There are no appropriate alternatives to issuing this NPRM because the ADA requires the Department of Justice to include standards in its regulations implementing subtitle A of title II of the ADA that are consistent with the minimum ADA guidelines issued by the Access Board. The Access Board’s accessibility guidelines will only become binding when the Department of Justice adopts them as legally enforceable requirements through rulemaking.

Anticipated Cost and Benefits: The Department anticipates costs to state and local governments given that this rule would require that the construction and alteration of pedestrian facilities in the public right-of-way comply with the Department’s accessibility requirements under subtitle A of title II of the ADA.

Risks: Failure to adopt requirements for the construction and alteration of pedestrian facilities covered by subtitle A of title II of the ADA that are consistent with the Access Board’s minimum Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way would mean that such Access Board guidelines would remain non-binding and unenforceable. It would also mean that the Department would not be complying with its obligation to...
ensure that the standards in its regulations are consistent with the minimum ADA guidelines issued by the Access Board.

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**Regulatory Flexibility Analysis**

**Required:** Undetermined.

**Small Entities Affected:** Governmental Jurisdictions.

**Government Levels Affected:** Local, State.

**Federalism:** Undetermined.

**Agency Contact:** Vivian Chu, Department of Justice, Civil Rights Division, 4 Constitution Square, 150 M Street NE, Washington, DC 20002, Phone: 202 305–2952.

**RIN:** 1140–AA54

**DOJ—BUREAU OF ALCOHOL, TOBACCO, FIREARMS, AND EXPLOSIVES (ATF)**

Final Rule Stage

104. Definition of “Frame or Receiver” and Identification of Firearms

**Priority:** Other Significant.


**Legal Deadline:** None.

**Abstract:** The Department of Justice proposes amending Bureau of Alcohol, Tobacco, Firearms, and Explosives regulations to provide new regulatory definitions of firearm frame or receiver and frame or receiver because they are outdated. The Department also proposes amending ATF’s definitions of firearm and gunsmith to clarify the meaning of those terms, and to add new regulatory terms such as complete weapon, complete muffler or silencer device, privately made firearm, and readily for purposes of clarity given advancements in firearms technology. Further, the Department proposes amendments to ATF’s definitions of firearm and stabilization equipment and modern terminology in the firearms industry, as well as amendments to the marking and recordkeeping requirements that would be necessary to implement these definitions.

**Statement of Need:** This rule is intended to clarify the meaning of firearm, frame or receiver so that those definitions more accurately reflect firearm configurations not explicitly captured under the existing definitions in 27 CFR 478.11 and 479.11. Further, this NPRM proposes new terms and definitions to take into account technological developments and modern terminology in the firearms industry, as well as amendments to the marking and recordkeeping requirements that would be necessary to implement these definitions.

**Summary of Legal Basis:** The Attorney General has express authority pursuant to 18 U.S.C. 926 to prescribe rules and regulations necessary to carry out the provisions of chapter 44, title 18, United States Code. The detailed legal analysis supporting the amendments in this rule are expressed in the abstract for the rule itself.

**Alternatives:** There are no feasible alternatives to the proposed rule that would allow ATF to maximize benefits.

**Anticipated Cost and Benefits:** The rule will not be economically significant; however, it is a significant regulatory action under section 3(f)(4) of Executive Order 12866 because this rule raises novel legal or policy issues arising out of legal mandates. ATF estimates that the costs for this proposed rule is minimal. The total 10-year undiscounted cost of this proposed rule is estimated to be $1.3 million. The total 10-year discounted cost of the rule is $1.0 million and $1.2 million at 7 percent and 3 percent, respectively. The annualized cost of this proposed rule would be $147,048 and $135,750, also at 3 percent and 7 percent, respectively.

**This rule provides for updated definitions to account for technological advances, ensures traceability regardless of age of firearm, and makes consistent marking requirements.**

**Risk:** Without this rule, public safety will continue to be threatened by the lack of traceability of firearms.

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**Regulatory Flexibility Analysis**

**Required:** No.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** None.

**Agency Contact:** Vivian Chu, Department of Justice, Bureau of Alcohol, Tobacco, Firearms, and Explosives, 99 New York Avenue NE, Washington, DC 20226, Phone: 202 648–7070.

**RIN:** 1140–AA54

**DOJ—ATF**

105. Factoring Criteria for Firearms With an Attached Stabilizing Brace

**Priority:** Other Significant.


**Legal Deadline:** None.

**Abstract:** The Department of Justice is planning to propose to amend the regulations of the Bureau of Alcohol, Tobacco, Firearms, and Explosives to set forth factors considered when evaluating firearms with an attached stabilizing brace to determine whether they are considered firearms under the National Firearms Act and/or the Gun Control Act.

**Statement of Need:** This rule is intended to clarify when a rifle is intended to be fired from the shoulder and to set forth factors that ATF considers when evaluating firearms with an attached purported stabilizing brace to determine whether these are rifles under the GCA or NFA, and therefore whether they are firearms subject to the NFA. It amends the definition of rifle in 27 CFR 478.11 and 479.11, respectively, by adding a sentence at the end of each definition. The new sentence would clarify that the term rifle includes any weapon with a rifled barrel and equipped with an attached stabilizing brace that has objective design features and characteristics that indicate that the firearm is designed to be fired from the shoulder, as indicated on ATF Worksheet 4999.

**Summary of Legal Basis:** The Attorney General has express authority pursuant to 18 U.S.C. 926 to prescribe rules and regulations necessary to carry out the provisions of chapter 44, title 18, United States Code. The detailed legal analysis supporting the amendments in this rule are expressed in the abstract for the rule itself.

**Alternatives:** There are no feasible alternatives to the proposed rule that would allow ATF to maximize benefits.

**Anticipated Cost and Benefits:** The rule is a significant regulatory action that is economically significant under section 3(f)(4) of Executive Order 12866, because the rule will have an annual effect on the economy of $10 million or more. The annualized cost of this proposed rule would be $114.7 million and $125.7 million, at 3 percent and 7 percent, respectively. This proposed rule would affect attempts by manufacturers and individuals to circumvent the requirements of the NFA and would affect the criminal use of...
weapons with a purported stabilizing brace.

**Risks:** Without this rule, public safety will continue to be threatened by the criminal use of such firearms, which are easily concealable from the public and first responders.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** None.

**International Impacts:** This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Agency Contact:** Denise Brown, Regulations Writer, Department of Justice, Bureau of Alcohol, Tobacco, Firearms, and Explosives, 99 New York Avenue NE, Washington, DC 20226, Phone: 202 648–7070.

**RIN:** 1140–AA55

**DOJ—Executive Office for Immigration Review (EOIR)**

**Proposed Rule Stage**

**106. Bars to Asylum Eligibility and Procedures**

**Priority:** Other Significant.


**CFR Citation:** 8 CFR 208; 8 CFR 1208; 8 CFR 1235; 8 CFR 1003.

**Legal Deadline:** None.

**Abstract:** In 2020, the Department of Homeland Security and Department of Justice (collectively, the Departments) published final rules amending their respective regulations governing bars to asylum eligibility and procedures, including the Procedures for Asylum and Bars to Asylum Eligibility, (RIN 1125–AA87 and 1116–AC41), 85 FR 67202 (Oct. 21, 2020), Asylum Eligibility and Procedural Modifications, (RINs 1125–AA91 and 1615–AC44), 85 FR 82260 (Dec. 17, 2020), and Security Bars and Processing, (RINs 1125–AB08 and 1615–AC57), 85 FR 84160 (Dec. 23, 2020), final rules.

The Departments propose to modify or rescind the regulatory changes promulgated in these three final rules, consistent with Executive Order 14010 (Feb. 2, 2021).

**Statement of Need:** The Departments are reviewing these regulations in light of the issuance of Executive Order 14010 and Executive Order 14012. This rule is needed to restore and strengthen the asylum system and to address inconsistencies with the goals and principles outlined in the Executive Order 14010 and Executive Order 14012.

**Summary of Legal Basis:** The Attorney General has general authority under 8 U.S.C. 1103(g) to establish regulations related to the immigration and naturalization of noncitizens. More specifically, under 8 U.S.C. 1158(b)(2)(C) and (d)(5)(B), the Attorney General has authority to provide by regulation additional conditions and limitations consistent with the INA for asylum eligibility. Thus, this proposed rule utilizes such authority to propose revisions to the regulations related to processing procedures for asylum and withholding of removal claims.

**Alternatives:** Unless the Departments rely on the pending litigation to enjoin Asylum and Bars to Asylum Eligibility, 85 FR 67202, and Asylum Eligibility and Procedural Modifications, 85 FR 82260, there are no other alternatives to revise those two rules. As for Security Bars and Processing, 85 FR 84160 (Dec. 23, 2020), because it relies on the framework for applying bars to asylum during credible fear processing that was established in an enjoined rule titled Procedures for Asylum and Withholding of Removal; Credible Fear and Reasonable Fear Review, 85 FR 80274, the only alternative is to wait for the outcome of that litigation before making changes to the regulation. Relying on litigation to address these rules could be extremely time-burdensome and may introduce confusion as to effectiveness of the regulations. Thus, the Departments consider this alternative to be a burdensome and inadvisable course of action and therefore not feasible.

**Anticipated Cost and Benefits:** DOJ and DHS are currently considering the specific cost and benefit impacts of the proposed provisions.

**Risks:** Without this rulemaking, regulations related to Procedures for Asylum and Bars to Asylum Eligibility, 85 FR 67202, and Asylum Eligibility and Procedural Modifications, 85 FR 82260, will remain enjoined pending litigation. This is inadvisable, as litigation typically takes much time to resolve. Moreover, implementation of Security Bars and Processing, 85 FR 80274, will not be viable (as described in the Alternatives section). Thus, the Department strongly prefers proactively addressing the regulations through this proposed rule.

**Timetable:**

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**DOJ—EOIR**

**107. Asylum and Withholding Definitions**

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.


**CFR Citation:** 8 CFR 2; 8 CFR 208; 8 CFR 1208.

**Legal Deadline:** None.

**Abstract:** This rule proposes to amend Department of Homeland Security (DHS) and Department of Justice (DOJ) regulations that govern eligibility for asylum and withholding of removal. The amendments focus on portions of the regulations that deal with the definitions of membership in a particular social group, the requirements for failure of State protection, and determinations about whether persecution is on account of a protected ground. This rule is consistent with Executive Order 14010 of February 2, 2021, which directs the Departments to, within 270 days, promulgate joint regulations, consistent with applicable law, addressing the circumstances in which a person should be considered a member of a particular social group.

**Statement of Need:** This rule provides guidance on a number of key interpretive issues of the refugee definition used by adjudicators deciding
asylum and withholding of removal (withholding) claims. The interpretive issues include whether persecution is inflicted on account of a protected ground, the requirements for establishing the failure of State protection, and the parameters for defining membership in a particular social group. This rule will aid in the adjudication of claims made by applicants whose claims fall outside of the rubric of the protected grounds of race, religion, nationality, or political opinion. One example of such claims which often fall within the particular social group ground concerns people who have suffered or fear domestic violence. This rule is expected to consolidate issues raised in a proposed rule in 2000 and to address issues that have developed since the publication of the proposed rule. This rule should provide greater stability and clarity in this important area of the law. This rule will also provide guidance to the following adjudicators: USCIS asylum officers, Department of Justice Executive Office for Immigration Review (EOIR) immigration judges, and members of the EOIR Board of Immigration Appeals (BIA).

Furthermore, on February 2, 2021, President Biden issued Executive Order 14010 that directs DOJ and DHS within 270 days of the date of this order, [to] promulgate joint regulations, consistent with applicable law, addressing the circumstances in which a person should be considered a member of a “particular social group,” as that term is used in 8 U.S.C. 1101(a)(42)(A), as derived from the 1951 Convention relating to the Status of Refugees and its 1967 Protocol.

Summary of Legal Basis: The purpose of this rule is to provide guidance on certain issues that have arisen in the context of asylum and withholding adjudications. The 1951 Geneva Convention relating to the Status of Refugees contains the internationally accepted definition of a refugee. United States immigration law incorporates an almost identical definition of a refugee as a person outside his or her country of origin “who is unable or unwilling to return to, and is unable or unwilling to avail himself or herself of the protection of, that country because of persecution or a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.” Section 101(a)(42) of the Immigration and Nationality Act.

Alternatives: Because this rulemaking is mandated by executive order to be completed within a short timeframe, there are no feasible alternatives at this time.

Anticipated Cost and Benefits: DOJ and DHS are currently considering the specific cost and benefit impacts of the proposed provisions. Risks: Without this rulemaking, the circumstances by which a person is considered a member of a particular social group will continue to be subject to judicial and agency interpretation, which may differ by circuit and changes in administration.

Timetable:

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Regulatory Flexibility Analysis
Required: Undetermined.

Government Levels Affected:
Undetermined.

Federalism: Undetermined.

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

URL For Public Comments: http://www.regulations.gov.

Agency Contact: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, Department of Justice, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 1800, Falls Church, VA 22041, Phone: 703 305–0289, Email: pao.eoir@usdoj.gov.

Related RIN: Related to 1125–AA94, Related to 1615–AC65, Related to 1615–AC42. 

RIN: 1125–AB13

DOJ—EOIR

108. Procedures for Asylum and Withholding of Removal

Priority: Other Significant.

Legal Authority: 8 U.S.C. 1103(g); 8 U.S.C. 1229a(c)(4)(B); 8 U.S.C. 1158(d)(5)(B)

CFR Citation: 8 CFR 1003.10; 8 CFR 1208; 8 CFR 1235; 8 CFR 1240.

Legal Deadline: None.

Abstract: On December 16, 2020, by the rule titled Procedures for Asylum and Withholding of Removal (RIN 1125–AA93) the Department of Justice (Department) amended the regulations governing asylum and withholding of removal, including changes to what must be included with an application for it to be considered complete and the consequences of filing an incomplete application, and changes related to the 180-day asylum adjudications clock. To revise the regulations related to adjudicatory procedures for asylum and withholding of removal, the Department is planning to rescind or modify the regulatory revisions made by that rule under this RIN.

Statement of Need: This proposed rule will revise the regulations related to adjudicatory procedures for asylum and withholding of removal. On December 16, 2020, the Department of Justice (Department) amended the regulations governing asylum and withholding of removal, including changes to what must be included with an application for it to be considered complete and the consequences of filing an incomplete application, and changes related to the 180-day asylum adjudications clock. Procedures for Asylum and Withholding of Removal, 85 FR 81698 (RIN 1125–AA93). In light of Executive Orders 14010 and 14012, 86 FR 8267 (Feb. 2, 2021) and 86 FR 8277 (Feb. 2, 2021), the Department reconsidered its position on those matters and now issues this proposed rule to revise the regulations accordingly.

Summary of Legal Basis: The Attorney General has general authority under 8 U.S.C. 1103(g) to establish regulations related to the immigration and naturalization of noncitizens. More specifically, under 8 U.S.C. 1158(d)(5)(B), the Attorney General has authority to provide by regulation additional conditions and limitations consistent with the INA for the consideration of asylum applications. Thus, this proposed rule utilizes such authority to propose revisions to the regulations related to adjudicatory procedures for asylum and withholding of removal pursuant, in part, to 8 U.S.C. 1229a(c)(4)(B).

Alternatives: Unless the Department relies on litigation to permanently enjoin the December 2020 rule, 85 FR 81698 (Dec. 16, 2020), there are no other alternatives to revise the regulations. Relying on litigation could be extremely time-consuming and may introduce confusion as to effectiveness of the regulations. Thus, the Department considers this alternative to be an inadequate and inadvisable course of action.

Anticipated Cost and Benefits: The Department believes this proposed rule will not be economically significant. The Department believes the costs to the public will be negligible, if any, given that costs will revert to those established prior to the December 2020 rule. This proposed rule imposes no new additional costs to the Department or to respondents: Respondents have always been required to complete asylum applications in order to have them adjudicated, and
immigration judges have always maintained the authority to set deadlines. In addition, this proposed rule proposes no new fees. The Department believes that this proposed rule would impose only minimal, if any, direct costs on the public. Any new minimal cost would be limited to the cost of the public familiarizing itself with proposed rule, although, as previously stated, the proposed rule reinstates most of the regulatory language to that which was in effect before the December 2020 rule. Further, an immigration judge’s ability to set filing deadlines is already established by regulation, and filing deadlines for both applications and supporting documents are already well-established aspects of immigration court proceedings guided by regulations and the OCIJ Practice Manual. Thus, the Department expects little in the proposed rule to require extensive familiarization.

Risks: Without this rulemaking, the regulations will remain enjoined pending litigation (as described in the Alternatives section). This is inadvisable, as litigation typically takes an inordinate time to resolve. The Department highly prefers proactively addressing the regulations through this proposed rule.

Timetable:

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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: None.

Additional Information: Related to EOIR Docket No. 19–0010.


URL For Public Comments: http://www.regulations.gov.

Agency Contact: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, Department of Justice, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 1800, Falls Church, VA 22041, Phone: 703 305–0289, Email: pao.eoir@usdoj.gov.

Related RIN: Related to 1125–AA93. RIN: 1125–AB15

DOJ—EOIR

109. Appellate Procedures and Decisional Finality in Immigration Proceedings: Administrative Closure

Priority: Other Significant.


CFR Citation: 8 CFR 1003.1; 8 CFR 1003.2; 8 CFR 1003.3; 8 CFR 1003.10.

Legal Deadline: None.

Abstract: On December 16, 2020, by a rule titled Appellate Procedures and Decisional Finality in Immigration Proceedings: Administrative Closure (RIN 1125–AA96) the Department of Justice (Department) amended its regulations regarding appellate procedures to ensure that immigration proceeding appeals are adjudicated in an efficient manner and to eliminate unnecessary removal by the Board of Immigration Appeals. The Department also amended its regulations to promote the final disposition of cases at both the immigration court and appellate levels. The Department is planning to modify or rescind those regulations under this RIN.

Statement of Need: On December 16, 2020, the Department of Justice (Department) amended the regulations related to processing of appeals and administrative closure. Appellate Procedures and Decisional Finality in Immigration Proceedings; Administrative Closure, 85 FR 81588 (RIN 1125–AA96). In light of Executive Orders 14010 and 14012, 86 FR 8267 (Feb. 2, 2021) and 86 FR 8277 (Feb. 2, 2021), the Department reconsidered its position on those matters and now issues this proposed rule to revise the regulations accordingly and make other related amendments. This proposed rule clarifies immigration judge and Board of Immigration Appeals (BIA) authority, including providing general administrative closure authority and the ability to sua sponte reopen and reconsider cases. The proposed rule also revises BIA standards involving adjudication timelines, briefing schedules, self-certification, remands, background checks, administrative notice, and voluntary departure. Lastly, the proposed rule removes the EOIR Director’s authority to issue decisions in certain cases, removes the ability of EOIR Director to certify cases for quality assurance, and revises procedures for the forwarding of the record on appeal, as well as other minor revisions.

Summary of Legal Basis: The Attorney General has general authority under 8 U.S.C. 1103(g) to establish regulations related to the immigration and naturalization of noncitizens. Thus, this proposed rule utilizes such authority to propose revisions to the regulations regarding immigration appeals processing and administrative closure.

Alternatives: Unless the Department relies on litigation to permanently enjoins the December 2020 rule, 85 FR 81588 (Dec. 16, 2020), there are no other alternatives to revise the regulations. Relying on litigation could be extremely time-burdensome and may introduce confusion as to effectiveness of the regulations. Thus, the Department considers this alternative to be an inadequate and inadvisable course of action.

Anticipated Cost and Benefits: The Department is largely reinstating the briefing schedules that the December 2020 rule revised. As stated in the December 2020 rule, 85 FR at 81650, the basic briefing procedures have remained across rules; thus, the Department believes the costs to the public will be negligible, if any, given that costs will revert back to those established for decades prior to the December 2020 rule. The proposed rule imposes no additional costs, as much of the proposed rule involves internal case processing. For those provisions that constitute more than simple internal case processing measures, such as the amendments to the BIA’s administrative closure authority, they likewise would not impose significant costs to the public. Indeed, such measures would generally reduce costs, as they facilitate and reintroduce various mechanisms for fair, efficient case processing.

Risks: Without this rulemaking, the regulations will remain enjoined pending litigation (as described in the Alternatives section). This is inadvisable, as litigation typically takes an inordinate time to resolve. The Department highly prefers proactively addressing the regulations through this proposed rule.

Timetable:

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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: None.

Additional Information: Related to EOIR Docket No. 19–0010.

DOJ—EOIR

Final Rule Stage

110. Professional Conduct for Practitioners—Rules and Procedures, and Representation and Appearances

Priority: Other Significant.
Legal Authority: 8 U.S.C. 1103; 8 U.S.C. 1326
CFR Citation: 8 CFR 1003.
Legal Deadline: None.
Abstract: This rule amends Department of Justice regulations addressing the assistance of individuals with the writing or filing of documents in proceedings before the Executive Office for Immigration Review. The rule also proposes to make minor technical revisions and to amend outdated references to the former Immigration and Naturalization Service.

Statement of Need: This rule would establish procedures for practitioners to provide individual document assistance without triggering the full obligations required of practitioners engaging in full representation of a noncitizen in EOIR proceedings.

Summary of Legal Basis: The Attorney General has general authority under 8 U.S.C. 1103(g) to establish regulations related to the immigration and naturalization of noncitizens. More specifically, under 8 U.S.C. 1158(b)(2)(C) and (d)(5)(B), the Attorney General has authority to provide by regulation additional conditions and limitations consistent with the INA for the consideration of asylum applications. Thus, this proposed rule utilizes such authority to propose revisions to the regulations related to processing procedures for asylum and withholding of removal claims pursuant to 8 U.S.C. 1225 and 1231.

DOJ—EOIR

111. Procedures for Credible Fear Screening and Consideration of Asylum, Withholding of Removal and CAT Protection Claims by Asylum Officers

Priority: Economically Significant.
CFR Citation: 8 CFR 208; 8 CFR 235; 8 CFR 1003; 8 CFR 1208; 8 CFR 1235.
Legal Deadline: None.
Abstract: The Department of Justice and the Department of Homeland Security (DHS) propose to amend the regulations so that individuals found to have a credible fear can have their claims for asylum, withholding of removal under section 241(b)(3) of the Immigration and Nationality Act (statutory withholding of removal), or protection under the regulations issued pursuant to the legislation implementing the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, initially adjudicated by an asylum officer within DHS with administrative review of the decision by the Executive Office for Immigration Review.

Statement of Need: There is wide agreement that the system for dealing with asylum and related protection claims at the southwest border has long been overwhelmed and in desperate need of repair. As the number of such claims has skyrocketed over the years, the system has proven unable to keep pace, resulting in large backlogs and lengthy adjudication delays. A system that takes years to reach a result delays justice and certainty for those who need protection, and it encourages abuse by those who will not qualify for protection and smugglers who exploit the delay for profit. The aim of this rule is to begin replacing the current system, within the confines of the law, with a better and more efficient one that will adjudicate protection claims fairly and expeditiously.

Summary of Legal Basis: The Attorney General has general authority under 8 U.S.C. 1103(g) to establish regulations related to the immigration and naturalization of noncitizens. More specifically, under 8 U.S.C. 1158(b)(2)(C) and (d)(5)(B), the Attorney General has authority to provide by regulation additional conditions and limitations consistent with the INA for the consideration of asylum applications. Thus, this proposed rule utilizes such authority to propose revisions to the regulations related to processing procedures for asylum and withholding of removal claims pursuant to 8 U.S.C. 1225 and 1231.

Alternatives: There are no feasible alternatives that make similarly impactful changes to the system without a more widespread overhaul of the entire system in one rulemaking.

Anticipated Cost and Benefits: DHS estimated the resource cost needed to implement and operationalize the rule along a range of possible future credible fear volumes. The average annualized costs could range from $179.5 million to $995.8 million at a 7 percent discount rate. At a 7 percent discount factor, the total ten-year costs could range from $1.3 billion to $7.0 billion, with a midrange of $3.2 billion.

There could also be cost-savings related to Forms I–589 and I–765 filing volume changes. In addition, some asylum applicants may realize potential early labor earnings, which could constitute a transfer from workers in the U.S. labor force to certain asylum applicants, as well as tax impacts. Qualitative benefits include, but may not be limited to: (i) Beneficiaries of new parole standards may not have to wait lengthy times for a decision on whether their asylum claims will...
receive further consideration; (ii) some individuals could benefit from de novo review by an IJ of the asylum officer’s denial of their asylum; (iii) DOJ–EOIR may focus efforts on other priority work and reduce its substantial current backlog; (iv) as some applicants may be able to earn income earlier than they otherwise could currently, burdens to the support network of the applicant may be lessened.

Risks: Without this rulemaking, the current system will remain status quo. The backlogs and delays will continue to grow, and potential for abuse will remain. Most importantly, noncitizens in need of protection will continue to experience delays in the adjudication of their claims.

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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: Undetermined.

Introduction
The Department’s Fall 2021 Regulatory Agenda continues to advance the Department’s mission to foster, promote, and develop the welfare of wage earners, job seekers, and retirees; improve working conditions; advance opportunities for profitable employment; and assure work-related benefits and rights. These rules will strengthen protections for some of the Nation’s most vulnerable workers, empower and support opportunities for advancement, secure our safety nets and advance equity and economic security.

In just the first months of the Biden Administration, the Department of Labor has begun historic rulemakings on issues central to workers in the United States and their families, including worker safety, protections from discrimination, fair wages, and retirement security and health care. These include the following rulemakings:

- We issued an Emergency Temporary Standard to help protect millions of frontline healthcare workers from exposure and spread of COVID–19, a virus that has already claimed the lives of over 750,000 people in the U.S. We also issued an Emergency Temporary Standard on Vaccination and Testing to protect more than 84 million additional workers from the consequences of COVID–19 exposure on the job. These science-based standards outline workplace safety protocols and will help save thousands of lives and prevents hundreds of thousands of hospitalizations.

- We finalized Interim Final Rules with the U.S. Department of Health and Human Services, the U.S. Department of Treasury, and the Office of Personnel Management to implement the No Surprises Act and protect people from unexpected medical expenses. Surprise billing can cause economic devastation for patients. This rule puts patients first by providing safeguards to keep families from financial ruin when they need medical care.

- We have also expeditiously withdrawn or rescinded rules as necessary to protect and strengthen workers’ economic security, including withdrawing the Independent Contractor Rule and rescinding the Joint Employer Rule.

The 2021 Regulatory Plan highlights the Labor Department’s most noteworthy and significant rulemaking efforts, with each addressing the top priorities of its regulatory agencies: Employee Benefits Security Administration (EBSA), Employment and Training Administration (ETA), Mine Safety and Health Administration (MSHA), Office of Federal Contract Compliance Programs (OFCCP), Occupational Safety and Health Administration (OSHA), Office of Workers’ Compensation Programs (OWCP), and Wage and Hour Division (WHD). These regulatory priorities exemplify the Secretary’s agenda to empower all workers morning, noon, and night, including:

- Investing in and valuing the nation’s care economy;
- Building a safe, modern, inclusive workforce; and
- Supporting a lifetime of worker empowerment.

Under Secretary Walsh’s leadership, the Department is committed to ensuring that equity, a strong foundation of evidence, and extensive stakeholder outreach are integral to all of our regulatory efforts. Our Regulatory Agenda additionally reflects our ongoing commitment to the Biden Administration’s prioritization of economic relief, raising wages, and addressing the threat of climate change, while embedding equity across the department’s agencies, policies, and programs.

Investing In and Valuing the Nation’s Care Economy
The Department’s regulatory priorities reflect the Secretary’s focus on care infrastructure to ensure workers have the opportunity and support to thrive in their jobs. That means ensuring workers can care for their families without risking their jobs, stay home when they’re sick or when they need to care for a sick family member, and have access to the resources they need to manage their mental health.

- EBSA’s rulemaking implementing the Mental Health Parity and Addiction Equity Act (MHPAEA) will strengthen health enforcement by clarifying plan and issuer obligations, promote compliance and address amendments to the Act from the Consolidated Appropriations Act of 2021.

In addition, OSHA will supplement its outreach and enforcement with rulemaking that protects employees in the care economy. Enhancing our care infrastructure starts with making sure our frontline care providers are safe on the job.

- OSHA will propose an Infectious Diseases rulemaking to protect employees in healthcare and other high risk environments from exposure to and transmission of persistent and new infectious diseases, ranging from ancient scourges such as tuberculosis to newer threats such as Severe Acute Respiratory Syndrome (SARS), the 2019 Novel Coronavirus (COVID–19), and other diseases.

- OSHA will initiate small business consultations as its first step in developing a Workplace Violence rulemaking, to provide protections for healthcare and other care economy workers, who are the most frequent victims of violence on the job.

Building a Safe, Modern, Inclusive Workforce
The Department’s regulatory priorities reflect the Secretary’s focus on ensuring people can have a good job and
opportunity for advancement. That means people can have a job that is safe, a job that pays a fair wage, a job that does not discriminate and that has opportunities for advancement. And that means a job where workers have a seat at the table and have a say in their work.

The Department’s health and safety regulatory proposals are aimed at eliminating preventable workplace injuries, illnesses and fatalities. Workplace safety also protects workers’ economic security, ensuring that illness and injury do not force families into poverty. Our efforts will prevent workers from having to choose between their lives and their livelihood.

- **OSHA** will propose a rulemaking on heat illness prevention. Increased temperatures are posing a serious threat to workers laboring outdoors and in non-climate controlled indoor settings. Exposure to excessive heat is not only a hazard in itself, causing heat illness and even death; it is also an indirect hazard linked to the loss of cognitive skills which can also lead to workplace injuries and worker deaths. OSHA will develop a standard to protect workers from these heat hazards in the workplace, helping to save lives while we confront the growing threat of climate change.

- **MSHA** will propose a new silica standard to effectively assess health concerns with a goal of ensuring that all miners are safe at their work places.

- **MSHA** will promulgate a rule establishing that mine operators must develop and implement a written safety program for surface mobile equipment used at surface mines and surface areas of underground mines, in order to provide safe environments for miners.

The Department’s regulatory agenda prioritizes workers’ economic security; ensures they receive a fair day’s pay for a fair day’s work, and do not face discrimination in hiring, employment, or benefits on the basis of race, gender, religion, disability, national origin, veteran’s status, sexual orientation, or gender identity. ETA, OFCCP and WHD will focus on regulatory changes that will have significant impact on workers of color, immigrant workers, and workers with disabilities.

- **OFCCP** is proposing to rescind certain provisions related to the religious exemption for federal contractors and subcontractors, ensuring that the religious exemption contained in Executive Order 11246 is applied consistently with nondiscrimination principles of Title VII of the Civil Rights Act of 1964, as amended.

- **OFCCP** will issue a proposal to modify the procedures for resolving potential employment discrimination, which is creating hurdles to effective enforcement.

- **WHD** issued regulations to implement President Biden’s executive order requiring federal contractors to pay a $15 minimum wage to hundreds of thousands of workers who are working on federal contracts. This will eliminate subminimum wages paid to some tipped workers and workers with disabilities, improve the economic security of families and make progress toward reversing decades of income inequality.

- **WHD** is proposing to update and modernize the regulations implementing the Davis Bacon and Related Acts to provide greater clarity and ensure workers are truly paid local prevailing wages on federal construction contracts.

- **WHD** will propose updates to the overtime regulations to ensure that middle class jobs pay middle class wages, extending important overtime pay protections to millions of workers and raising their pay.

- **WHD** engaged in rulemaking to ensure the economic security of tipped workers.

- **ETA** will ensure fair wages and strengthened protections for foreign and U.S. workers under the H-1B/H-2A visa programs through regulatory changes.

The Department is committed to ensuring workers have opportunities for employment and training and advancement in their jobs.

- **ETA** will ensure job-seekers can more easily get the support they need by proposing changes to the Wagner-Peyser Employment Service regulations.

- **ETA** is focused on ensuring high-quality apprenticeship programs, and as part of this, has proposed rescinding Industry Recognized Apprenticeship Programs (IRAP) rules and suspending further application review efforts for new IRAP Standard Recognition Entities in order to renew focus on Registered Apprenticeship.

The Department is committed to ensuring workers have a seat at the table and furthering this Administration’s support for unions and workers who are organizing unions, which are critical to achieving economic fairness and racial and gender justice. **Supporting a Lifetime of Worker Empowerment**

We are focused on making sure people do not have to worry that the loss of a job or need for medical care will destroy their financial well-being. People should be able to save for retirement, access health care, and have the support they need to get through a personal or family crisis or when they become injured or ill on the job.

- **EBSA** will support the administration’s agenda to address the threat of climate change by implementing two executive orders that increase transparency in climate-related financial investment options. To carry out Executive Order 13990 “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,” and Executive Order 14030, “Climate-Related Financial Risks,” EBSA is proposing to remove provisions of the current regulation that inappropriately discourage consideration of environmental, social, and governance issues by fiduciaries in making investment and proxy voting decisions, and provide further clarity that would help safeguard the interests of participants and beneficiaries in the plan benefits.

**DOL—OFFICE OF FEDERAL CONTRACT COMPLIANCE PROGRAMS (OFCCP)**

**Proposed Rule Stage**

**112. Proposal To Rescind Implementing Legal Requirements Regarding the Equal Opportunity Clause’s Religious Exemption**

**Priority:** Other Significant.

**Legal Authority:** E.O. 11246

**CFR Citation:** 41 CFR 60–1.

**Legal Deadline:** None.

**Abstract:** The Office of Federal Contract Compliance Programs is proposing to rescind the December 8, 2020, final rule, “Implementing Legal Requirements Regarding the Equal Opportunity Clause’s Religious Exemption” (85 FR 79324), which would include the removal of certain definitions at 41 CFR 60–1.3 related to the religious exemption and 41 CFR 60–1.5(e) and (f). The rescission would ensure that the religious exemption contained in section 204(c) of Executive Order 11246 is consistent with nondiscrimination principles of Title VII of the Civil Rights Act of 1964, as amended. The notice of proposed rescission was published on November 9, 2021.

**Statement of Need:** The Office of Federal Contract Compliance Programs issued a proposal to rescind the regulations established in the final rule titled Implementing Legal Requirements Regarding the Equal Opportunity Clause’s Religious Exemption and returning to the agency’s traditional approach, which applies Title VII principles and applicable case law and thus will promote clarity and consistency in the application of the religious exemption.
113. Modification of Procedures To Resolve Potential Employment Discrimination

Priority: Other Significant.

Legal Authority: E.O. 11246; 29 U.S.C. 793; 38 U.S.C. 4216

CFR Citation: 41 CFR 60–1, 60–2, 60–4, 60–20, 60–30; 41 CFR 60–40, 60–50, 60–300, 60–741.

Legal Deadline: None.

Abstract: This proposal would modify certain provisions set forth in the November 10, 2020 final rule, Nondiscrimination Obligations of Federal Contractors and Subcontractors: Procedures To Resolve Potential Employment Discrimination (85 FR 71553) and make other related changes to the pre-enforcement notice and conciliation process. The proposal will promote effective enforcement through OFCCP’s regulatory procedures.

Statement of Need: The Office of Federal Contract Compliance Programs intends to issue a Proposed Rule to modify regulations that delineate procedures and standards the agency follows when issuing pre-enforcement notices and securing compliance through conciliation. This proposal would support OFCCP in fulfilling its mission to ensure equal employment opportunity.

Summary of Legal Basis: Executive Order 11246 (as amended), section 503 of the Rehabilitation Act (as amended), and the Vietnam Era Veterans’ Readjustment Assistance Act (as amended).

Alternatives: To be determined.

Anticipated Cost and Benefits: The OFCCP considered the anticipated costs and benefits associated with the proposed rule.

Risks: To be determined.

Timetable:

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<td>01/08/21</td>
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<td>11/09/21</td>
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DOL—WAGE AND HOUR DIVISION

114. Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees

Proposed Rule Stage

Priority: Economically Significant.

Major under 5 U.S.C. 801.

Unfunded Mandates: Undetermined.


CFR Citation: 29 CFR 541.

Legal Deadline: None.

Abstract: WHD is reviewing the regulations at 29 CFR 541, which implement the exemption of bona fide executive, administrative, and professional employees from the Fair Labor Standards Act’s minimum wage and overtime requirements.

Statement of Need: One of the primary goals of this rulemaking would be to update the salary level requirement of the section 13(a)(1) exemption. A salary level test has been part of the regulations since 1938 and it has been long recognized that the best test of the employer’s good faith in attributing to the employee’s services is the amount he pays for them. In prior rulemakings, the Department explained its commitment to update the standard salary level and Highly Compensated Employees (HCE) total compensation levels more frequently. Regular updates promote greater stability, avoid disruptive salary level increases that can result from lengthy gaps between updates and provide appropriate wage protection.

Summary of Legal Basis: Section 13(a)(1) of the FLSA, codified at 29 U.S.C. 213(a)(1), exempts any employee employed in a bona fide executive, administrative, or professional capacity or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary, subject to the provisions of the [Administrative Procedure Act.]) The FLSA does not define the terms executive, administrative, professional, or outside salesman. However, pursuant to Congress’ grant of rulemaking authority, the Department issued regulations at 29 CFR part 541, defining the scope of the section 13(a)(1) exemptions. Congress explicitly delegated to the Secretary of Labor the power to define and delimit the specific terms of the exemptions through notice-and-comment rulemaking.

Alternatives: Alternatives will be developed in considering proposed revisions to the current regulations. The public will be invited to provide comments on the proposed revisions and possible alternatives.

Anticipated Cost and Benefits: The Department will prepare estimates of the anticipated costs and benefits associated with the proposed rule.

Risks: This action does not affect public health, safety, or the environment.

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DOl—WHD

115. Modernizing the Davis-Bacon and Related Acts Regulations


Unfunded Mandates: Undetermined.


CFR Citation: 29 CFR 1; 29 CFR 3; 29 CFR 5; 29 CFR 6; 29 CFR 7.

Legal Deadline: None.

Abstract: The Davis-Bacon Act (DBA) was enacted in 1931 and amended in 1935 and 1964. The DBA requires the payment of locally prevailing wages and fringe benefits to laborers and mechanics as determined by the Department of Labor. The DBA applies to direct Federal contracts and District of Columbia contracts in excess of $2,000 for the construction, alteration, or repair of public buildings and public works. Congress has included DBA prevailing wage requirements in numerous statutes (referred to as Related Acts) under which Federal agencies assist construction projects through grants, loans, guarantees, insurance, and other methods. Covered contractors and subcontractors must pay their laborers and mechanics employed under the contract no less than the locally prevailing wage rates and fringe benefits as required by the applicable wage determination. The Department proposes to update and modernize the regulations implementing the Davis-Bacon and Related Acts to provide greater clarity and enhance their usefulness in the modern economy.

Statement of Need: The Department proposes to update and modernize the regulations implementing the Davis-Bacon and Related Acts to provide greater clarity and enhance their usefulness in the modern economy.

Summary of Legal Basis: These regulations are authorized by Title 40, sections 3141–3148. Minimum wages are defined as those determined by the Secretary to be (a) prevailing; (b) in the locality of the project; (c) for similar craft and skills; (d) on comparable construction work. See section 3142.

Alternatives: Alternatives will be developed in considering proposed revisions to the current regulations. The public will be invited to provide comments on the proposed revisions and possible alternatives.

Anticipated Cost and Benefits: The Department will prepare estimates of the anticipated costs and benefits associated with the proposed rule.

Risks: This action does not affect public health, safety, or the environment.

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DOl—WHD

116. Tip Regulations Under the Fair Labor Standards Act (FLSA)


Unfunded Mandates: This action may affect the private sector under Public Law 104-4.


Legal Deadline: None.

Abstract: In the Consolidated Appropriations Act of 2018 (“CAA”), Congress amended section 3(m) of the Fair Labor Standards Act ("FLSA") to prohibit employers from keeping tips received by their employees, regardless of whether the employers take a tip credit under section 3(m). Congress also amended section 16(e) of the FLSA to allow the Department to impose civil money penalties ("CMPs") when employers unlawfully keep employees’ tips. On December 30, 2020, the Wage and Hour Division ("WHD") published Tip Regulations Under the Fair Labor Standards Act (the “2020 Tip final rule”) in the Federal Register to address these amendments and to codify guidance regarding the FLSA tip credit’s application to employees who perform tipped and non-tipped duties. The effective date of the 2020 Tip final rule was March 1, 2021, but the Department extended that date until April 30, 2021, in accordance with the Presidential directive as expressed in the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff. The Department further delayed three portions of the 2020 Tip final rule until December 31, 2021: Two portions addressing the assessment of CMPs and the portion addressing the application of the FLSA tip credit to tipped employees who perform tipped and non-tipped duties. The Department proposed to withdraw these three portions of the 2020 Tip final rule and proposed new language addressing these three issues. On September 24, 2021, a Department final rule (CMP final rule) was published in the Federal Register, which among other things, adopted language upholding the Department’s statutorily-granted discretion with regard to tip section 3(m)(2)(B) CMPs, and aligned the Department’s regulations with the FLSA’s statutory text. On June 23, 2021, the Department published an NPRM (Dual Jobs NPRM) in the Federal Register, 86 FR 32818, proposing to withdraw and repropose the portion of the 2020 Tip final rule addressing when a tipped employee performs both tipped and non-tipped duties under the FLSA. The comment period closed on August 23, 2021. The Department published a final rule on October 29, 2021 to finalize its proposal to withdraw one portion of the Tip Regulations Under the FLSA (2020 Tip final rule) and finalize its proposed revisions related to the determination of when a tipped employee is employed in dual jobs. Specifically, the Department amended its regulations to clarify that an employer may only take a tip credit when its tipped employees perform work that is part of the employee’s tipped occupation.

Statement of Need: Upon review of the portion of the 2020 Tip final rule addressing when a tipped employee performs both tipped and non-tipped duties under the FLSA, the Department was concerned that the lack of clear guidelines in the rule regarding when a tipped employee who is performing non-tipped duties is still engaged in a tipped occupation, such that an employer can continue to take a tip credit for the time the tipped employee spends on such non-tipped work failed...
to achieve its goal of providing certainty for employers and created the potential for the misuse of the FLSA tip credit. Among other things, the 2020 Tip final rule would have permitted an employer to take a tip credit for time that an employee in a tipped occupation spends performing related, non-tipped duties contemporaneously with tipped duties, or for a reasonable time immediately before or after performing the tipped duties. The Department believes that because the 2020 Tip final rule did not define these key terms, the 2020 Tip final rule will invite rather than limit litigation in this area, and thus may not support one of the rule’s stated justifications for departing from established guidance. The Dual Jobs final rule clarifies that an employer may only take a tip credit when its tipped employees perform work that is part of the employee’s tipped occupation.

Summary of Legal Basis: The Fair Labor Standards Act (FLSA or Act) generally requires employers to pay employees at least the federal minimum wage, which is currently $7.25 per hour. See 29 U.S.C. 206(a)(1). Section 3(m) of the FLSA allows an employer that meets certain requirements to take a credit toward its minimum wage obligations of a limited amount, currently up to $5.12 per hour, of the tips received by employees (known as a tip credit). See 29 U.S.C. 203(m)(2)(A). Section 3(t) of the FLSA defines a tipped employee for whom an employer may take a tip credit under section 3(m) as any employee engaged in an occupation in which he customarily and regularly receives more than $30 a month in tips. See 29 U.S.C. 203(t). The FLSA regulations addressing tipped employment are codified at 29 CFR 531.50 through 531.60. See also 29 CFR 10.28 (establishing a tip credit for federal contractor employees covered by Executive Order 13658 who are tipped employees under section 3(t) of the FLSA).

Alternatives: The Department issued this final rule upon a reasoned determination that its benefits justify its costs; and that it is tailored to impose the least burden on society, consistent with obtaining the regulatory objectives; and that, in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some costs and benefits are difficult to quantify and provides that, when appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts. The analysis in the final rule outlines the impacts that the Department anticipates may result from this rule.

Anticipated Cost and Benefits: The Department believes that the revisions to its regulations regarding when a tipped employee is employed in dual jobs provides increased clarity to employers and workers and ensures workers are paid the wages they are owed. In the Dual Jobs final rule, the Department estimated that these changes would lead to costs for Year 1 that will consist of rule familiarization costs, adjustment costs, and management costs, and would be $224,882,399 ($23,827,236 + $23,827,236 + $177,227,926). For the following years, the Department estimates that costs will only consist of management costs and would be $177,227,926. Additionally, the Department estimated average annualized costs of this rule over 10 years. Over 10 years, it will have an average annual cost of $183.6 million calculated at a 7 percent discount rate ($151.1 million calculated at a 3 percent discount rate). All costs are in 2019 dollars.

Risks: This action does not affect public health, safety, or the environment.

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<td>85 FR 86756</td>
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Regulatory Flexibility Analysis

Required: Undetermined.

Small Entities Affected: Businesses.

Government Levels Affected: None.

Agency Contact: Amy DeBisschop, Director of the Division of Regulations, Legislation, and Interpretation.

Department of Labor, Wage and Hour Division, 200 Constitution Avenue NW, FP Building, Room S–3502, Washington, DC 20210, Phone: 202 693–0406.

RIN: 1235–AA21
117. E.O. 14026, Increasing the Minimum Wage for Federal Contractors

Priority: Economically Significant.
Major under 5 U.S.C. 801.
Unfunded Mandates: This action may affect the private sector under Public Law 104–4.
Legal Authority: E.O. 14026
CFR Citation: 29 CFR 23; 29 CFR 10.
Legal Deadline: None.
Abstract: On April 27, 2021, President Joseph Biden issued E.O. 14026, Increasing the Minimum Wage for Federal Contractors to promote economy and efficiency in procurement by increasing the hourly minimum wage rate paid by parties that contract with the Federal Government to $15.00 for those employees working on or in connection with a Federal Government contract. These regulations will implement the Executive Order.

Statement of Need: President Biden issued Executive Order 14026 pursuant to his authority under the Constitution and the laws of the United States, expressly including the Federal Property and Administrative Services Act (Procurement Act), 40 U.S.C. 101 et seq. The Executive order directs the Secretary to issue regulations by November 24, 2021, consistent with applicable law, to implement the order’s requirements.

Summary of Legal Basis: The Procurement Act authorizes the President to prescribe policies and directives that the President considers necessary to carry out the statutory purposes of ensuring economical and efficient government procurement and administration of government property. 40 U.S.C. 101, 121(a). Executive Order 14026 delegates to the Secretary the authority to issue regulations to implement the requirements of this order. 86 FR 22835. The Executive order directs the Secretary to issue regulations by November 24, 2021, consistent with applicable law, to implement the order’s requirements.

Alternatives: The Department noted that due to the prescriptive nature of Executive Order 14026, the Department does not have the discretion to implement alternatives that would violate the text of the Executive order, such as the adoption of a higher or lower minimum rate, or continued exemption of recreational businesses. However, the Department considered several alternatives to discretionary proposals set forth in this final rule. In the final rule, the Department proposed to define the term United States, when used in a geographic sense, to mean the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Outer Continental Shelf lands as defined in the Outer Continental Shelf Lands Act, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Wake Island, and Johnston Island.

The Department considered defining the term United States to exclude contracts performed in the territories listed above, consistent with the discretionary decision made in the Department’s prior rulemaking implementing Executive Order 13658. Such an alternative would result in fewer contracts covered by Executive Order 14026 and fewer workers entitled to an initial $15 hourly minimum wage for work performed on or in connection with such contracts. This alternative was rejected because the Department has further examined the issue since its prior rulemaking in 2014 and consequently determined that the Federal Government’s procurement interests in economy and efficiency would be promoted by extending the Executive Order 14026 minimum wage to workers performing on or in connection with covered contracts.

A second alternative the Department considered in the final rule was raising (or eliminating) the 20 percent threshold for an exclusion for FLSA-covered workers performing in connection with covered contracts. If the Department were to omit this exclusion, more workers would be covered by the rule, and contractors would be required to pay more workers the applicable minimum wage rate (initially $15 per hour) for time spent performing in connection with covered contracts. This would result in greater income transfers to workers. Conversely, if the Department were to raise the 20 percent threshold, fewer workers would be covered by the rule, resulting in a smaller income transfer to workers.

The Department rejected this regulatory alternative because having an exclusion for FLSA-covered workers performing in connection with covered contracts based on a 20 percent of hours worked in a week standard is a reasonable interpretation.

Anticipated Cost and Benefits: In the final rule, the Department estimated the number of employees who would, as a result of the Executive order and the proposed rule, see an increase in their hourly wage, i.e., affected employees. The Department estimates there will be 327,300 affected employees in the first year of implementation (Table 1 of final rule). During the first 10 years the rule is in effect, average annualized direct employer costs are estimated to be $2.4 million (Table 1 of final rule) assuming a 7 percent real discount rate (hereafter, unless otherwise specified, average annualized values will be presented using a 7 percent real discount rate). This estimated annualized cost includes $1.9 million for regulatory familiarization and $538,500 for implementation costs. Other potential costs are discussed qualitatively.

The direct transfer payments associated with this rule are transfers of income from employers to employees in the form of higher wage rates. Estimated average annualized transfer payments are $1.75 billion per year over 10 years.

The Department expects that increasing the minimum wage of Federal contract workers will generate several important benefits. However, due to data limitations, these benefits are not monetized. As noted in the Executive order, the NPRM will promote economy and efficiency. Specifically, the proposed rule discusses benefits from improved government services, increased morale and productivity, reduced turnover, reduced absenteeism, and reduced poverty and income inequality for Federal contract workers.

Risks: This action does not affect public health, safety, or the environment.

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Regulatory Flexibility Analysis

Required: No.

Government Levels Affected: None.

Agency Contact: Amy DeBisschop, Director of the Division of Regulations, Legislation, and Interpretation, Department of Labor, Wage and Hour Division, 200 Constitution Avenue NW, FP Building, Room S–3502, Washington, DC 20210, Phone: 202 693–0406.

RIN: 1235–AA41
118. Wagner–Peyser Act Staffing

**Priority:** Other Significant.

**Legal Authority:** Wagner–Peyser Act

**CFR Citation:** 20 CFR 651; 20 CFR 652; 20 CFR 653; 20 CFR 658.

**Legal Deadline:** None.

**Abstract:** The Department proposes to revise the Wagner–Peyser Act regulations regarding Employment Services (ES) staffing to require that states use state merit staff to provide ES services, including Migrant and Seasonal Farmworker (MSFW) services, and to improve service delivery for migrant and seasonal farmworkers (MSFW).

**Statement of Need:** The Department has identified areas of the regulation that should be changed to create a uniform standard of ES services provision for all States.

**Summary of Legal Basis:** The Department is undertaking this rulemaking pursuant to its authority under the Wagner–Peyser Act.

**Alternatives:** Two alternatives will be considered, and the public will have the opportunity to comment on these alternatives after publication of the NPRM.

**Anticipated Cost and Benefits:** The proposed rule is expected to have one-time rule familiarization costs of $4,205 in 2020 dollars, as well as unknown transition costs. The proposed rule is also expected to have annual transfer payments of $9.6 million for three of the five States that currently have non-State merit staff providing some labor exchange services. In the NPRM, the Department will solicit comments from stakeholders and the public on the unknown transition costs, plus transfer payments that would be incurred by the two additional States with some non-State merit staff providing labor exchange services.

**Risks:** This action does not affect the public health, safety, or the environment.

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**Regulatory Flexibility Analysis Required:** Undetermined.

**Government Levels Affected:** Undetermined.

**Agency Contact:** John V. Ladd, Administrator, Office of Apprenticeship, Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW, FP Building, Room C–5311, Washington, DC 20210, Phone: 202 693–3799, Fax: 202 693–3799, Email: ladd.john@dol.gov. RIN: 1205–AC06

119. Apprenticeship Programs, Labor Standards for Registration, Amendment of Regulations

**Priority:** Economically Significant.

**Major under 5 U.S.C. 801.**

**Legal Authority:** The National Apprenticeship Act, as amended (50 Stat. 664) 29 U.S.C. 50

**CFR Citation:** 29 CFR 29.

**Legal Deadline:** None.

**Abstract:** On February 17, 2021, the President signed an Executive Order: (1) Revoking Executive Order 13801 (issued on June 15, 2017); and (2) directing federal departments and agencies to consider taking steps promptly to rescind any orders, rules, regulations, guidelines or policies implementing Executive Order 13801. The Department is considering amending its apprenticeship regulations to rescind subpart B of title 29 CFR part 29, Labor Standards for the Registration of Apprenticeship Programs, including the status of those Standards Recognition Entities and Industry Recognized Apprenticeship Programs (IRAPs) that previously received recognition under the provisions of 29 CFR part 29, subpart B, and to make additional conforming edits in subpart A as appropriate.

**Statement of Need:** Executive Order 14016 (86 FR 11089), issued by the President on February 17, 2021, directed Federal agencies to promptly consider taking steps to rescind any orders, rules, regulations, guidelines, or policies implementing E.O. 13801. In response to E.O. 14016, the Department has reviewed the IRAP system and has determined that, because the IRAP system has fewer quality training and worker protection standards than the Registered Apprenticeship system and results in a duplicative system of apprenticeship, it will issue a proposed regulation to rescind subpart B of title 29 CFR part 29, Labor Standards for the Registration of Apprenticeship Programs.

**Summary of Legal Basis:** The National Apprenticeship Act of 1937 (NAA), 29 U.S.C. 50, authorizes the Secretary of Labor (Secretary) to: (1) Formulate and promote the use of labor standards necessary to safeguard the welfare of apprentices and to encourage their inclusion in apprenticeship contracts; (2) bring together employers and labor for the formulation of programs of apprenticeship; and (3) cooperate with State agencies engaged in the formulation and promotion of standards of apprenticeship.

**Alternatives:** Alternatives were proposed in the NPRM that is open for public comment.

**Anticipated Cost and Benefits:** The Department’s preliminary estimates is anticipated cost savings of $8.9 million over the first 10 years of the proposed rule (2022–2031). Details for costs and benefits will be prepared.

**Risks:** This action does not affect the public health, safety, or the environment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Undetermined.

**Government Levels Affected:** Undetermined.

**Agency Contact:** Kimberly Vitelli, Regulatory Flexibility Analysis, 202 693–3980, Email: vitelli.kimberly@dol.gov. RIN: 1205–AC02
policies set forth in section 1 of the orders 86 FR 7037 (January 25, 2021); 86 FR 27967 (May 25, 2021). Such policies include the promotion and protection of public health and the environment and ensuring that agency activities are guided by the best science and protected by processes that ensure the integrity of Federal decision-making, and to advance consistent, clear, intelligible, comparable, and accurate disclosure of climate-related financial risk, including both physical and transition risks.

Section 2 of E.O. 13990 provides that for any such regulatory actions identified by the agencies, the heads of agencies shall, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding the agency actions. Section 4 of E.O. 14030 directs the Secretary of Labor to consider publishing, by September 2021, for notice and comment a proposed rule to suspend, revise, or rescind “Financial Factors in Selecting Plan Investments,” 85 FR 72846 (November 13, 2020), and “Fiduciary Duties Regarding Proxy Voting and Shareholder Rights,” 85 FR 81658 (December 16, 2020). The Department of Labor’s Employee Benefits Security Administration therefore will undertake a review of regulations under title I of the Employee Retirement Income Security Act in accordance with these orders, including “Financial Factors in Selecting Plan Investments,” 85 FR 72846 (November 13, 2020), and “Fiduciary Duties Regarding Proxy Voting and Shareholder Rights,” 85 FR 81658 (December 16, 2020).

Statement of Need: The Department of Labor’s Employee Benefits Security Administration undertook a review of the “Financial Factors in Selecting Plan Investments” and the “Fiduciary Duties Regarding Proxy Voting and Shareholder Rights,” final rules in accordance with Executive Order 13990 and Executive Order 14030. Those final rules were intended to provide clarity and certainty regarding the scope and application of ERISA fiduciary duties to plan investment decisions and to the exercise of shareholder rights, including proxy voting. Stakeholder reactions to the 2020 rules, however, suggest that the rules may have caused more confusion than clarity. Many interested stakeholders have expressed concerns that the terms and tone of the rules and related preambles have increased uncertainty about the extent to which plan fiduciaries may take into account environmental, social, or governance (ESG) considerations, including climate-related financial risk, in their investment and proxy voting decisions, and that the final rules have and will continue to have chilling effects contrary to the financial interests of ERISA plans and their participants and beneficiaries. The NPRM is needed to address these concerns and negative impacts.

Summary of Legal Basis: The Department is proposing the amendments pursuant to ERISA sections 404 (29 U.S.C. 1104) and 505 (29 U.S.C. 1135), and Executive Order 14030 (86 FR 27967 (May 25, 2021)) and Executive Order 13990 (86 FR 7037 (January 25, 2021)).

Alternatives: The Department considered various alternatives, including leaving the current regulations in place without change, rescinding the Financial Factors in Selecting Plan Investments and Fiduciary Duties Regarding Proxy Voting and Shareholder Rights final rules, and revising the current regulation by, in effect, reverting it to its form before the 2020 final rules.

Anticipated Cost and Benefits:—The primary benefit of the proposal is clarification of legal standards, which should empower fiduciaries to take proper account of ESG factors when making investment decisions and exercising proxy voting rights on behalf of plan participants. The Department has heard from stakeholders that the current regulation, and investor confusion about it, has already had a chilling effect on appropriate integration of ESG factors in investment decisions, and could deter plan fiduciaries from taking into account ESG factors even when they are material to a risk-return analysis. Stakeholders also indicated that confusion surrounding the current regulation could discourage proxy voting and other exercises of shareholder rights even when doing so is in the plan’s best interest. A significant benefit of this proposal would be to ensure that plans do not inappropriately avoid considering material ESG factors when selecting investments or exercising shareholder rights, as they might otherwise be inclined to do under the current regulation. Acting on material ESG factors in these contexts, and in a manner consistent with the proposal, will redound, in the first instance, to employee benefit plans covered by ERISA and their participants and beneficiaries, and secondarily and indirectly, to society more broadly but without any sacrifices by the participants and beneficiaries in ERISA plans. Further, by ensuring that plan fiduciaries would not sacrifice investment returns or take on additional investment risk to promote unrelated goals, this proposal would lead to increased investment returns over the long run. The proposal would also make certain that ERISA regulation would not chill or otherwise discourage proxy voting by plans governed by the economic interests of the plan and its participants. This would promote management accountability to shareholders, including the affected shareholder plans. These benefits, while difficult to quantify, are anticipated to outweigh the costs.

Anticipated Costs—By reversing aspects of the current regulation, this proposal would facilitate certain activities among plan fiduciaries in their investment decisions, including potential changes in asset management strategies and proxy voting behavior, that these plan fiduciaries otherwise likely would not take under the current regulation. The precise impact of this proposal on such behavior is uncertain. Therefore, a precise quantification of all costs similarly is not possible. To the extent that the proposal changes investment-related behavior among ERISA plans, its benefits are expected to outweigh the costs. Overall, the costs of the proposal are expected to be relatively small, in part because the Department assumes most plan fiduciaries are complying with the pre-2020 interpretive bulletins to the extent relevant to costs (specifically Interpretive Bulletin 2016–1 and 2015–1), and it is expected that the proposal would track that guidance to a very large extent. Known incremental costs of the proposal would be minimal on a per-plan basis.

Risks: The risk of not pursuing this rulemaking is that, if the current regulation is not amended, it could have a) a negative impact on plans’ financial performance as they avoid materially sound ESG investments or integration of material ESG considerations in investment analysis, b) a negative impact on plans’ financial performance as they shy away from economically relevant considerations in proxy voting and from exercising shareholder rights on material issues, and c) broader negative economic/societal impacts (e.g., negative impacts on climate change and on corporate managers’ accountability to the shareholders who own the companies they serve).

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<td>10/14/21</td>
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DOL—EBSA

121. * Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021

Priority: Other Significant.
CFR Citation: Not Yet Determined.
Legal Deadline: None.
Abstract: This rule would propose amendments to the final rules implementing the Mental Health Parity and Addiction Equity Act (MHPAEA). The amendments would clarify plans’ and issuers’ obligations under the law, promote compliance with MHPAEA, and update requirements to take into account experience with MHPAEA in the years since the rules were finalized as well as amendments to the law recently enacted as part of the Consolidated Appropriations Act, 2021.
Statement of Need: There have been a number of legislative enactments related to MHPAEA since issuance of the 2014 final rules, including the 21st Century Cures Act, the Support Act, and the Consolidated Appropriations Act, 2021. This rule would propose amendments to the final rules and incorporate examples and modifications to account for this legislation and previously issued guidance and to take into account experience with MHPAEA in the years since the rules were finalized.
Summary of Legal Basis: The Department of Labor regulations would be adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).
Alternatives: Not yet determined.
Anticipated Cost and Benefits: Not yet determined.
Risks: Not yet determined.

Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: Undetermined.
Agency Contact: Jeffrey J. Turner, Deputy Director, Office of Regulations and Interpretations, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, FP Building, Room N–5655, Washington, DC 20210, Phone: 202 693–8500.
RIN: 1210–AC03

DOL—EBSA

122. Requirements Related to Surprise Billing, Part 1

Priority: Economically Significant.
Legal Authority: Pub. L. 116–260, Division BB, Title I and Title II
CFR Citation: Not Yet Determined.
Abstract: This interim final rule with comment would implement certain protections against surprise medical bills under the No Surprises Act, including requirements on group health plans, issuers offering group or individual health insurance coverage, providers, facilities, and providers of air ambulance services.
Statement of Need: Surprise bills can cause significant financial hardship and cause individuals to forgo care. The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise medical bills arise most frequently. These interim final rules fulfill a rulemaking requirement under the No Surprises Act and protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.
Summary of Legal Basis: The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).
Agency Contact: Amber Rivers, Director, Office of Health Plan Standards and Compliance Assistance, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Washington, DC 20210, Phone: 202 693–8335, Email: rivers.amber@dol.gov.
RIN: 1210–AC11

Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: State.
Federalism: This action may have federalism implications as defined in E.O. 13132.

Alternatives: In developing the interim final rules, the Departments considered various alternative approaches, including whether cost-sharing should be based on the recognized amount in circumstances where the billed charge is lower, whether plans and issuer should take into account the number of claims paid at the contracted rate when calculating the qualifying payment amount, and many others.
Anticipated Cost and Benefits: The provisions in these interim final rules will ensure that participants, beneficiaries, and enrollees with health coverage are protected from surprise medical bills. Individuals with health coverage will gain peace of mind, experience a reduction in out-of-pocket expenses, be able to meet their deductible and out-of-pocket maximum limits sooner, and may experience increased access to care. Plans, issuers, health care providers, facilities, and providers of air ambulance services will incur costs to comply with the requirements in these interim final rules.
Risks: The risk of not pursuing this rulemaking is that the Department would fail to meet its statutory obligations to issue regulations, group health plans would lack guidance needed to comply with the statutory requirements, and individuals would continue to be burdened by surprise medical bills.

Timetable:

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<th>Action</th>
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Regulatory Flexibility Analysis
Required: Yes.
Small Entities Affected: Businesses.
Government Levels Affected: Federal, State.
Federalism: This action may have federalism implications as defined in E.O. 13132.

Agency Contact: Amber Rivers, Director, Office of Health Plan Standards and Compliance Assistance, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Washington,
DOL—EBSA

123. Requirements Related to Surprise Billing, Part 2

Priority: Economically Significant.
Citation: Not Yet Determined.

Abstract: This interim final rule with comment would implement additional protections against surprise medical bills under the No Surprises Act, including provisions related to the independent dispute resolution processes.

Statement of Need: Surprise bills can cause significant financial hardship and cause individuals to forgo care. The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise medical bills arise most frequently. These interim final rules implement provisions of the No Surprises Act related to the independent dispute resolution process for settling payment disputes and protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.

Summary of Legal Basis: The Department of Labor regulations are contained in 29 CFR 1135, 1182.

Interim Final Rule

Effective.

Interim Final Rule Comment Period End.

Regulatory Flexibility Analysis

Required: Undetermined.
Government Levels Affected: Federal, State.
Agency Contact: Amber Rivers, Director, Office of Health Plan Standards and Compliance Assistance, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Washington, DC 20210, Phone: 202 693–8335, Email: rivers.amber@dol.gov. RIN: 1210–AC90

DOL—MINE SAFETY AND HEALTH ADMINISTRATION (MSHA)

124. Respirable Crystalline Silica

Priority: Other Significant.
Legal Authority: 30 U.S.C. 811; 813(h); 30 U.S.C. 957
Citation: 30 CFR 56; 57; 72; 200.

Summary of Legal Basis: Sections 101(11), 103(h), and 508 of the Federal Mine Safety and Health Act of 1977 (Mine Act), as amended (30 U.S.C. 811(a), 813(h), and 957).

Alternatives: MSHA will examine one or two different levels of miners’ RCS exposure limit and assess the technological and economic feasibility of such option(s).

Anticipated Cost and Benefits: To be determined.

Risks: Miners face impairment risk of health and functional capacity due to RCS exposures. MSHA will examine the existing RCS standard and determine ways to reduce the health risks associate with RCS exposure.

Regulatory Flexibility Analysis

Required: Undetermined.
Small Entities Affected: Businesses, Governmental Jurisdictions.
Government Levels Affected: Local, State.
Agency Contact: Jessica Senk, Director, Office of Standards, Regulations, and Variances, Department of Labor, Mine Safety and Health Administration, 201 12th Street S, Suite
DOL—MSHA

125. Safety Program for Surface Mobile Equipment


CFR Citation: 30 CFR 56; 30 CFR 57; 30 CFR 77.

Legal Deadline: None.

Abstract: MSHA would require mine operators to establish a written safety program for mobile equipment and powered haulage equipment (except belt conveyors) used at surface mines and surface areas of underground mines. Under this proposal, mine operators would be required to assess hazards and identify actions to reduce accidents related to surface mobile equipment. The operators would have flexibility to develop and implement a safety program that would work best for their mining conditions and operations. This proposed rule is to reduce fatal and nonfatal injuries involving surface mobile equipment used at mines and to improve miner safety and health.

Statement of Need: Although mine accidents are declining, accidents involving mobile and powered haulage equipment are still a leading cause of fatalities in mining. To reduce fatal and nonfatal injuries involving surface mobile equipment used at mines, MSHA is proposing a regulation that would require mine operators employing six or more miners to develop a written safety program for mobile and powered haulage equipment (excluding belt conveyors) at surface mines and surface areas of underground mines. The written safety program would include actions mine operators would take to identify hazards and risks to reduce accidents, injuries, and fatalities related to surface mobile equipment.

Summary of Legal Basis: Sections 101(a), 103(h), and 508 of the Federal Mine Safety and Health Act of 1977 (Mine Act), as amended (30 U.S.C. 811(a), 813(h), and 957).

Alternatives: MSHA considered requiring all mines, regardless of size, to develop and implement a written safety program for surface mobile equipment. Based on the Agency's experience, MSHA concluded that a mine operator with five or fewer miners would generally have a limited inventory of surface mobile equipment. These operators would also have less complex mining operations, with fewer mobile equipment hazards that would necessitate a written safety program. Thus, these mine operators are not required to have a written safety program, although MSHA would encourage operators with five or fewer miners to have safety programs. MSHA will consider comments and suggestions received on alternatives or best practices that all mines might use to develop safety programs (whether written or not) for surface mobile equipment.

Anticipated Cost and Benefits: The proposed rule would not be economically significant, and it would have some net benefits.

Risks: Miners operating mobile and powered haulage equipment or working nearby face risks of workplace injuries, illnesses, or deaths. The proposed rule would allow a flexible approach to reducing hazards and risks specific to each mine so that mine operators would be able to develop and implement safety programs that work for their operation, mining conditions, and miners.

Timetable:

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<th>Action</th>
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<td>Request for Information (RFI)</td>
<td>06/26/18</td>
<td>83 FR 29716</td>
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<td>Notice of Public Stakeholder Meetings</td>
<td>07/25/18</td>
<td>83 FR 35157</td>
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<td>Stakeholder Meeting—Birmingham, AL.</td>
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<td>Stakeholder Meeting—Dallas, TX.</td>
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<td>Stakeholder Meeting (Webinar)—Arlington, VA.</td>
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<td>Stakeholder Meeting—Reno, NV.</td>
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<td>Stakeholder Meeting—Beckley, WV.</td>
<td>09/11/18</td>
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<td>Stakeholder Meeting—Albany, NY.</td>
<td>09/20/18</td>
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<td>Stakeholder Meeting—Arlington, VA.</td>
<td>09/25/18</td>
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<td>12/24/19</td>
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<td>09/09/21</td>
<td>86 FR 50496</td>
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<td>11/08/21</td>
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<td>10/00/22</td>
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Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Agency Contact: Jessica Senk, Director, Office of Standards, Regulations, and Variances, Department of Labor, Mine Safety and Health Administration, 201 12th Street S, Suite 201, Arlington, VA 22202, Phone: 202 693–9440.

RIN: 1219–AB36

DOL—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

Prerule Stage

126. Prevention of Workplace Violence in Health Care and Social Assistance


Unfunded Mandates: Undetermined.

Legal Authority: 29 U.S.C. 655(b); 5 U.S.C. 609

CFR Citation: Not Yet Determined.

Legal Deadline: None.

Abstract: The Request for Information (RFI) (published on December 7, 2016 81 FR 80147) provides OSHA's history with the issue of workplace violence in health care and social assistance, including a discussion of the Guidelines that were initially published in 1996, a 2014 update to the Guidelines, the agency's use of 5(a)(1) in enforcement cases in health care. The RFI solicited information primarily from health care employers, workers and other subject matter experts on impacts of violence, prevention strategies, and other information that will be useful to the agency. OSHA was petitioned for a standard preventing workplace violence in health care by a broad coalition of labor unions, and in a separate petition by the National Nurses United. On January 10, 2017, OSHA granted the petitions. OSHA is preparing for SBREFA.

Statement of Need: Workplace violence is a widespread problem, and there is growing recognition that workers in healthcare and social service occupations face unique risks and challenges. In 2018, the rate of serious workplace violence incidents (those requiring days off for an injured worker to recuperate) was more than five times greater in these occupations than in private industry on average, with both the number and share of incidents rising faster in these professions than among other workers.

Healthcare and social services account for nearly as many serious violent injuries as all other industries combined. Workplace violence comes at a high cost. It harms workers often both physically and emotionally and makes it more difficult for them to do their jobs.

Workers in some medical and social service settings are more at risk than others. According to the Bureau of Labor Statistics, in 2018 workers at psychiatric substance abuse hospitals
experienced the highest rate of violent injuries that resulted in days away from work, at approximately 125 injuries per 10,000 full-time employees (FTEs). This is about 6 times the rate for workers at nursing and residential care facilities (21.1/10,000). But even workers involved in ambulatory care, while less likely than other healthcare workers to experience violent injuries, were 1.5 times as likely as workers outside of healthcare to do so.

Summary of Legal Basis: The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

Alternatives: One alternative to proposed rulemaking would be to take no regulatory action. As OSHA develops more information, it will also make decisions relating to the scope of the standard and the requirements it may impose.

Anticipated Cost and Benefits: The estimates of costs and benefits are still under development.

Risks: Analysis of risks is still under development.

Timetable:

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<td>81 FR 88147</td>
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<td>04/06/17</td>
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<td>12/00/21</td>
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Regulatory Flexibility Analysis Required: Yes.

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations.

Government Levels Affected: Local, State.

Agency Contact: Andrew Levinson, Deputy Director, Directorate of Standards and Guidance, Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue NW, FP Building, Room N–3718, Washington, DC 20210, Phone: 202 693–1950, Email: levinson.andrew@ dol.gov.

RIN: 1218–AD08

DOL—OSHA

127. Heat Illness Prevention in Outdoor and Indoor Work Settings

Priority: Other Significant.

Legal Authority: Not Yet Determined

CFR Citation: None.

Legal Deadline: None.

Abstract: Heat is the leading weather-related killer, and it is becoming more dangerous as 18 of the last 19 years were the hottest on record. Excessive heat can cause heat stroke and even death if not treated properly. It also exacerbates existing health problems like asthma, kidney failure, and heart disease. Workers in agriculture and construction are at highest risk, but the problem affects all workers exposed to heat, including indoor workers without climate-controlled environments. Essential jobs where employees are exposed to high levels of heat are disproportionately held by Black and Brown workers.

Heat stress killed 815 US workers and seriously injured more than 70,000 workers from 1992 through 2017, according to the Bureau of Labor Statistics. However, this is likely a vast underestimate, given that injuries and illnesses are under reported in the US, especially in the sectors employing vulnerable and often undocumented workers. Further, heat is not always recognized as a cause of heat-induced injuries or deaths and can easily be misclassified, because man of the symptoms overlap with other more common diagnoses.

To date, California, Washington, Minnesota, and the US military have issued heat protections. OSHA currently relies on the general duty clause (OSH Act Section 5(a)(1)) to protect workers from this hazard. Notably, from 2013 through 2017, California used its heat standard to conduct 50 times more inspections resulting in a heat-related violation than OSHA did nationwide under its general duty clause. It is likely to become even more difficult to protect workers from heat stress under the general duty clause in light of the 2019 Occupational Safety and Health Review Commission’s decision in Secretary of Labor v. A.H. Sturgill Roofing, Inc. OSHA was petitioned by Public Citizen for a heat stress standard in 2011. The Agency denied this petition in 2012, but was once again petitioned by Public Citizen, on behalf of approximately 130 organizations, for a heat stress standard in 2018 and 2019. Most recently in 2021, Public Citizen petitioned OSHA to issue an emergency temporary standard on heat stress. OSHA is still considering these petitions and has neither granted nor denied to date. In 2019 and 2021, some members of the Senate also urged OSHA to initiate rulemaking to address heat stress.

Given the potentially broad scope of regulatory efforts to protect workers from heat hazards, as well as a number of technical issues and considerations with regulating this hazard (e.g., heat stress thresholds, heat acclimation planning, exposure monitoring, medical monitoring), a Request for Information would allow the agency to begin a dialogue and engage with stakeholders to explore the potential for rulemaking on this topic.

Statement of Need: Heat stress killed more than 900 US workers, and caused serious health illness in almost 100 times as many, from 1992 through 2019, according to the Bureau of Labor Statistics. However, this is likely a vast underestimate, given that injuries and illnesses are underreported in the US, especially in the sectors employing vulnerable and often undocumented workers. Further, heat is not always recognized as a cause of heat-induced illnesses or deaths, which are often misclassified, because many of the symptoms overlap with other more common diagnoses. Moreover, climate change is increasing the heat hazard throughout the nation: 2020 was either the hottest or the second hottest year on record, with 2021 on track to be even hotter. Although official figures are not yet available, we already know that in many states heat related deaths are higher are far higher than normal this year.

Summary of Legal Basis: The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

Alternatives: One alternative to proposed rulemaking would be to take no regulatory action. As OSHA develops more information, it will also make decisions relating to the scope of the standard and the requirements it may impose.

Anticipated Cost and Benefits: The estimates of costs and benefits are still under development.

Risks: Analysis of risks is still under development.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined.

Government Levels Affected: Undetermined.

Agency Contact: Andrew Levinson, Deputy Director, Directorate of Standards and Guidance, Department of Labor, Occupational Safety and Health
128. Infectious Diseases

Proposed Rule Stage

DOL—OSHA

128. Infectious Diseases

Priority: Economically Significant.

Major status under 5 U.S.C. 801 is undetermined.

Unfunded Mandates: Undetermined.


Legal Deadline: None.

Abstract: Employees in health care and other high-risk environments face long-standing infectious disease hazards such as tuberculosis (TB), varicella disease (chickenpox, shingles), and measles, as well as new and emerging infectious disease threats, such as Severe Acute Respiratory Syndrome (SARS), the 2019 Novel Coronavirus (COVID–19), and pandemic influenza. Health care workers and workers in related occupations, or who are exposed in other high-risk environments, are at increased risk of contracting TB, SARS, Methicillin-Resistant Staphylococcus Aureus (MRSA), COVID–19, and other infectious diseases that can be transmitted through a variety of exposure routes.

Summary of Legal Basis: The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

Alternatives: One alternative is to take no regulatory action. OSHA is examining regulatory alternatives for control measures to protect employees from infectious disease exposures to pathogens that can cause significant disease. In addition to health care, workplaces where SERs suggested such control measures might be necessary include: Emergency response, correctional facilities, homeless shelters, drug treatment programs, and other occupational settings where employees can be at increased risk of exposure to potentially infectious people.

A standard could also apply to laboratories, which handle materials that may be a source of pathogens, and to pathologists, coroners’ offices, medical examiners, and mortuaries.

Statement of Need: Employees in health care and other high-risk environments face long-standing infectious disease hazards such as tuberculosis (TB), varicella disease (chickenpox, shingles), and measles, as well as new and emerging infectious disease threats, such as Severe Acute Respiratory Syndrome (SARS), the 2019 Novel Coronavirus (COVID–19), and pandemic influenza. Health care workers and workers in related occupations, or who are exposed in other high-risk environments, are at increased risk of contracting TB, SARS, Methicillin-Resistant Staphylococcus Aureus (MRSA), COVID–19, and other infectious diseases that can be transmitted through a variety of exposure routes.

Summary of Legal Basis: The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

Alternatives: One alternative is to take no regulatory action. OSHA is examining regulatory alternatives for control measures to protect employees from infectious disease exposures to pathogens that can cause significant disease. In addition to health care, workplaces where SERs suggested such control measures might be necessary include: Emergency response, correctional facilities, homeless shelters, drug treatment programs, and other occupational settings where employees can be at increased risk of exposure to potentially infectious people.

A standard could also apply to laboratories, which handle materials that may be a source of pathogens, and to pathologists, coroners’ offices, medical examiners, and mortuaries.

OSHA offered several alternatives to the SBREFA panel when presenting the proposed Infectious Disease (ID) rule. OSHA considered a specification oriented rule rather than a performance oriented rule, but has preliminarily determined that this type of rule would provide less flexibility and would likely fail to anticipate all of the potential hazards and necessary controls for every type and every size of facility and would under-protect workers. OSHA also considered changing the scope of the rule by restricting the ID rule to workers who have occupational exposure during the provision of direct patient care in institutional settings but based on the evidence thus far analyzed, workers performing other covered tasks in both institutional and non-institutional settings also face a risk of infection because of their occupational exposure.

Anticipated Cost and Benefits: The estimates of costs and benefits are still under development.

Risks: Analysis of risks is still under development.

Timetable:

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<td>Analyze Comments</td>
<td>12/30/10</td>
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Regulatory Flexibility Analysis

Required: Yes.

Small Entities Affected: Businesses, Governmental Jurisdictions.

Government Levels Affected: Local, State.

Federalism: Undetermined.

Agency Contact: Andrew Levinson, Deputy Director, Directorate of Standards and Guidance, Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue NW, FP Building, Room N–3718, Washington, DC 20210, Phone: 202 693–1950, Email: levinson.andrew@dol.gov.

RIN: 1218–AD39

BILLING CODE 4510–HL–P

DEPARTMENT OF TRANSPORTATION (DOT)

Introduction: Department Overview

DOT has statutory responsibility for ensuring the United States has the safest and most efficient transportation system in the world. To accomplish this goal, DOT regulates safety in the aviation, motor carrier, railroad, motor vehicle, commercial space, transit, and pipeline transportation areas. The Department also regulates aviation consumer and economic issues and provides financial assistance and writes the necessary implementing rules for programs involving highways, airports, mass transit, the maritime industry, railroads, motor transportation and vehicle safety. DOT also has responsibility for developing policies that implement a wide range of regulations that govern Departmental programs such as acquisition and grants management, access for people with disabilities, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, security, emergency response, and the use of aircraft and vehicles. In addition, DOT writes regulations to carry out a variety of statutes ranging from the Air Carrier Access Act and the Americans
with Disabilities Act to Title VI of the Civil Rights Act. The Department carries out its responsibilities through the Office of the Secretary (OST) and the following operating administrations (OAs): Federal Aviation Administration (FAA); Federal Highway Administration (FHWA); Federal Motor Carrier Safety Administration (FMCSA); Federal Railroad Administration (FRA); Federal Transit Administration (FTA); Maritime Administration (MARAD); National Highway Traffic Safety Administration (NHTSA); Pipeline and Hazardous Materials Safety Administration (PHMSA); and Great Lakes St. Lawrence Seaway Development Corporation (GLS).

The Department’s Regulatory Philosophy and Initiatives

The U.S. Department of Transportation (Department or DOT) issues regulations to ensure the United States transportation system is the safest in the world, and addresses other urgent challenges the Nation, including the coronavirus disease 2019 (COVID–19) pandemic, job creation, equity, and climate change. These issues are addressed, in part, by encouraging innovation, thereby ensuring that the Department’s regulations keep pace with the latest developments and reflect its top priorities.

The Department’s actions are also governed by several recent executive orders issued by the President, which direct agencies to utilize all available regulatory tools to address pressing national challenges. On January 20, 2021, the President signed Executive Order 13992, Revocation of Certain Executive Orders Concerning Federal Regulation. This Executive Order directs Federal agencies to promptly take steps to rescind any orders, rules, regulations, guidelines, or policies that would hamper the agencies’ flexibility to use robust regulatory action to address national priorities. On January 20, 2021, the President also issued Executive Order 13990, Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis. This Executive Order directs Federal agencies to review all regulatory actions issued in the previous Administration and revise or rescind any of those actions that do not adequately respond to climate change, protect the environment, advance environmental justice, or improve public health.


On July 9, 2021, the President signed Executive Order 14036, Promoting Competition in the American Economy. Among other things, this Executive Order requires the Department to enhance consumer access to airline flight information and ensure that consumers are not exposed or subject to advertising, marketing, pricing, and charging of ancillary fees that may constitute an unfair or deceptive practice or an unfair method of competition. This Executive Order also requires the Department to: (1) Publish a notice of proposed rulemaking (NPRM) requiring airlines to refund baggage fees when a passenger’s luggage is substantially delayed and other ancillary fees when passengers pay for a service that is not provided; and (2) consider initiating a rulemaking to ensure that consumers have ancillary fee information, including “baggage fees,” “change fees,” and “cancellation fees,” at the time of ticket purchase.

On August 5, 2021, the President signed Executive Order 14037, Strengthening American Leadership in Clean Cars and Trucks. This Executive Order requires that the Department consider beginning work on a rulemaking to establish new fuel economy standards for passenger cars and light-duty trucks beginning with model year 2027 and extending through and including at least model year 2030. This Executive Order also requires the Department to consider beginning work on a rulemaking to establish new fuel economy standards for heavy-duty pickup trucks and vans beginning with model year 2028 and extending through and including at least model year 2030. Finally, this Executive Order requires the Department to consider beginning work on a rulemaking to establish new fuel economy standards for medium- and heavy-duty engines and vehicles to begin as soon as model year 2030.

In response to Executive Order 13992, in April 2021, the Department issued a final rule revising the regulations governing its regulatory process to ensure that it has the maximum flexibility necessary to quickly respond to the urgent challenges facing our Nation. Following implementation of the final rule, in June 2021, the Secretary signed a Departmental Order strengthening the Department’s internal rulemaking procedures and revitalizing the partnership between Operating Administrations and the Office of the Secretary in promulgating regulations to better achieve the Department’s goals and priorities. As part of this critical overhaul, a Regulatory Leadership Group was established, led by the Deputy Secretary of Transportation, which provides vital legal and policy guidance on the Department’s regulatory agenda.

In response to Executive Order 13990, in May 2021, the Department issued an NPRM proposing to repeal the SAFE I Rule and associated guidance documents. In August 2021, the Department issued a Supplemental Notice of Proposed Rulemaking inviting comments on the appropriate path forward regarding civil penalties imposed on violations of DOT’s vehicle emissions rules. Finally, in September 2021, the Department issued an NPRM proposing more stringent vehicle emission limits than those set by the SAFE II Rule.

The Department’s regulatory activities also remain directed toward protecting safety for all persons. Safety is a pressing national concern and our highest priority; the Department remains focused on managing safety risks and ensuring that the United States has the safest and most efficient transportation system in the world. This focus is as urgent as ever; after decades of declines in the number of fatalities on our roads, the United States has been seeing a recent increase in fatalities among pedestrians, bicyclists, and vehicle occupants that must be reversed. Similarly, we must address disparities in how the burden of these safety risks fall on different communities.

The Department’s Regulatory Priorities

The regulatory plan laid out below reflects a careful balance that emphasizes the Department’s priorities in responding to the urgent challenges facing our nation.

Safety. Safety is our North Star. The DOT Regulatory Plan reflects this commitment to safety through a balanced regulatory approach grounded in reducing transportation-related...
fatalities and injuries. Our goals are to manage safety risks, reverse recent trends negatively affecting safety, and build on the successes that have already been achieved to make our transportation system safer than it has ever been. Innovations should reduce deaths and serious injuries on our Nation’s transportation network, while committing to the highest standards of safety across technologies. For example, the Department is working on two rulemakings to require or standardize equipment performance for automatic emergency braking on heavy trucks and newly manufactured light vehicles. Responding to the COVID–19 Pandemic. The Department is providing rapid response and emergency review of legal and operational challenges presented by COVID–19 and its associated burdens within the transportation sector and among the traveling public. DOT is also addressing regulatory compliance made impracticable by the COVID–19 public health emergency due to facility closures, personnel shortages, and other restrictions.

Economic Growth. The safe and efficient movement of goods and passengers requires us not just to maintain, but to improve our national transportation infrastructure. But that cannot happen without changes to the way we plan, fund, and approve projects. Accordingly, our Regulatory Plan incorporates regulatory actions that increase competition and consumer protection, as well as streamline the approval process and facilitate more efficient investment in infrastructure, which is necessary to maintain global leadership and foster economic growth.

Climate Change. Climate change is one of the most urgent challenges facing our nation. The Department has engaged in multiple regulatory activities to address this challenge. As discussed earlier, the Department is actively engaged in updating its regulations with the goal of reducing emissions. The Department is also engaged in rulemakings to measure and reduce emissions from transportation projects and improve safety related to movement of natural gas. Equity. Ensuring that the transportation system equitably benefits underserved communities is a top priority. As discussed earlier, the Department is urgently working to address the threat of climate change, which is a burden often disproportionately borne by underserved communities. This work is guided by the Departmental and interagency work being done pursuant to Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. The Department is also working on a rulemaking that would make it easier for members of underserved communities to apply to and be a part of the Disadvantaged Business Enterprise (DBE) and Airport Concession DBE Program. In addition, the Department is working on multiple rulemakings to ensure access to transportation for people with disabilities. For example, the Department is working on a rulemaking to ensure that people with disabilities can access lavatories on single-aisle aircraft, and it has commenced a rulemaking to ensure that disabled persons have equitable access to transit facilities. All OAs are prioritizing their regulatory actions in accordance with Executive Orders 13985, 13990, and 13992 to make sure they are providing the highest level of safety while responding to the urgent challenges facing our Nation. Since each OA has its own area of focus, we summarize the regulatory priorities of each below. More information about each of the rules discussed below can be found in the DOT Unified Agenda.

Office of the Secretary of Transportation

OST oversees the regulatory processes for the Department. OST implements the Department’s regulatory policies and procedures and is responsible for ensuring the involvement of senior officials in regulatory decision making. Through the Office of the General Counsel, OST is also responsible for ensuring that the Department complies with the Administrative Procedure Act, Executive Orders 12866 and 13563, DOT’s Regulatory Policies and Procedures, and other legal and policy requirements affecting the Department’s rulemaking activities. In addition, OST has the lead role in matters concerning aviation consumer and economic rules. Title VI of the Civil Rights Act, the Americans with Disabilities Act, and rules that affect multiple elements of the Department.

OST provides guidance and training regarding compliance with regulatory requirements and processes for personnel throughout the Department. OST also plays an instrumental role in the Department’s efforts to improve our economic analyses; risk assessments; regulatory flexibility analyses; other related analyses; retrospective reviews of rules; and data quality, including peer reviews. The Office of the General Counsel (OGC) is the lead office that works with the Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) to comply with Executive Order 12866 for significant rules, coordinates the Department’s response to OMB’s intergovernmental review of other agencies’ significant rulemaking documents, and other relevant Administration rulemaking directives. OGC also works closely with representatives of other agencies, the White House, and congressional staff to provide information on how various proposals would affect the ability of the Department to perform its safety, infrastructure, and other missions.

In July 2021, the President issued Executive Order 14036, which directed the Department to take actions that would promote competition and deliver benefits to America’s consumers, including potentially initiating a rulemaking to ensure that air consumers have ancillary fee information, including “baggage fees,” “change fees,” and “cancellation fees,” at the time of ticket purchase. Among a number of steps to further the Administration’s goals in this area, the Department has initiated a rulemaking to enhance consumers’ ability to determine the true cost of travel, titled “Enhancing Transparency of Airline Ancillary Service Fees.” In addition, OST will further enhance its airline passenger protections through the rulemaking initiatives required by Executive Order 14036.

Advancing equity in air transportation for individuals with disabilities is also a priority for the Administration. To further this goal, the Department is developing a rulemaking to improve the accessibility of lavatories on single-aisle aircraft. In this rulemaking, the Department is considering options to significantly improve the ability of passengers with disabilities to travel with freedom and dignity by being able to access the lavatory.

Federal Aviation Administration

FAA is charged with safely and efficiently operating and maintaining the most complex aviation system in the world. To enhance aviation safety, FAA is finalizing a rulemaking that would require certain airport certificate holders to develop, implement, maintain, and adhere to a safety management system.
FAA is also developing a proposal to reduce risks caused by latent defects in critical systems on transport category airplanes. The FAA will continue to advance rulemakings to ensure that the United States has the safest aviation, most efficient, and modern aviation system in the world, including proposing a rulemaking that would require certain aircraft, engine, and propeller manufacturers; certificate holders conducting common carriage operations; certain maintenance providers; and persons conducting certain, specific types of air tour operations to implement a Safety Management System. FAA will also manage rulemakings to further advance the integration of unmanned aircraft systems and commercial space operations into the national airspace system. In addition, the FAA will propose requirements for the certification of certain airplanes to enforce compliance with the emissions standards adopted by the Environmental Protection Agency under the Clean Air Act.

Federal Highway Administration

FHWA carries out the Federal highway program in partnership with State and local agencies to meet the Nation’s transportation needs. FHWA’s mission is to improve the quality and performance of our Nation’s highway system and its intermodal connectors. Consistent with this mission, FHWA is scheduled to update the Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD), conforming technical provisions of the 2009 edition to reflect advances in technologies and operational practices that are not currently allowed in the MUTCD. This update will incorporate the latest human factors research to make road signage more accessible, thereby ensuring that both pedestrians and vehicles comply with that signage and reduce the risk of an accident. The Agency will also pursue a new rulemaking requiring safety integration across all Federal-aid programs and any necessary mitigation on Federal-aid projects. In addition, FHWA will work on a rulemaking to establish a method for the measurement and reporting of greenhouse gas emissions associated with transportation.

Federal Motor Carrier Safety Administration

The mission of FMCSA is to reduce crashes, injuries, and fatalities involving commercial motor vehicles. A strong regulatory program is a cornerstone of FMCSA’s compliance and enforcement efforts to advance this safety mission. In addition to Agency-directed regulations, FMCSA develops regulations mandated by Congress, through legislation such as the Moving Ahead for Progress in the 21st Century (MAP–21) and the Fixing America’s Surface Transportation (FAST) Acts. FMCSA regulations establish minimum safety standards for motor carriers, commercial drivers, commercial motor vehicles, and State agencies receiving certain motor carrier safety grants and issuing commercial drivers’ licenses.

FMCSA will continue to coordinate efforts on the development of autonomous vehicle technologies and review existing regulations to identify changes that might be needed to ensure that DOT regulations ensure safety and keep pace with innovations. Additionally, in support of the National Highway Traffic Safety Administration’s (NHTSA) automatic emergency braking (AEB) rulemaking for heavy trucks, FMCSA will seek information and comment concerning the maintenance and operation of AEB by motor carriers.

National Highway Traffic Safety Administration

The mission of NHTSA is to save lives, prevent injuries, and reduce economic costs due to roadway crashes. The statutory responsibilities of NHTSA relating to motor vehicles include reducing the number, and mitigating the effects, of motor vehicle crashes and related fatalities and injuries; providing safety-relevant information to aid prospective purchasers of vehicles, child restraints, and tires; and improving light-, medium-, and heavy-duty vehicle fuel efficiency requirements. NHTSA pursues policies that enable safety, climate and energy policy and conservation, equity, and mobility. NHTSA develops safety standards and regulations driven by data and research, including those mandated by Congress under the MAP–21 Act, the FAST Act, and the Energy Independence and Security Act, among others. NHTSA’s regulatory priorities for Fiscal Year 2022 focus on issues related to safety, climate, equity, and vulnerable road users.

To enhance the safety of vulnerable road users and vehicle occupants, NHTSA plans to issue a proposal to require automatic emergency braking (AEB) on light vehicles, including Pedestrian AEB. For heavy trucks, NHTSA also plans to propose to require AEB. For climate and equity, NHTSA plans to complete a rulemaking to address greenhouse fuel economy (CAFE) preemption, pursuant to Executive Order 13990. Improving fuel economy for light, medium and heavy-duty vehicles can have significant public health impacts, especially for overburdened communities. NHTSA also plans to issue a final rule for Model Year 2024–2026 CAFE standards for passenger cars and light trucks. More information about these rules can be found in the DOT Unified Agenda.

Federal Railroad Administration

FRA exercises regulatory authority over all areas of railroad safety and, where feasible, incorporates flexible performance standards. The current FRA regulatory program continues to reflect a number of pending proceedings to satisfy mandates resulting from the Rail Safety Improvement Act of 2008 (RSIA08), the Passenger Rail Investment and Improvement Act of 2008 (PRIIA), and the FAST Act. These actions support a safe, high-performing passenger rail network, address the safe and effective movement of energy products, and encourage innovation and the adoption of new technology in the rail industry to improve safety and efficiencies. FRA’s regulatory priority for Fiscal Year 2022 is to propose regulations addressing the issue of the requirements for safe minimum train crew size depending on the type of operation.

Federal Transit Administration

The mission of FTA is to improve public transportation for America’s communities. To further that end, FTA provides financial and technical assistance to local public transit systems, including buses, subways, light rail, commuter rail, trolleys, and ferries, oversees safety measures, and helps develop next-generation technology research. FTA’s regulatory activities implement the laws that apply to recipients’ uses of Federal funding and the terms and conditions of FTA grant awards.

In furtherance of its mission and consistent with statutory changes, in Fiscal Year 2022, FTA will update its Buy America regulation to incorporate changes to the waiver process made by MAP–21 and the FAST Act and to make other conforming updates and amendments. FTA will also modify its Bus Testing regulation to improve testing procedures and to respond to technological advancements in vehicle testing. Finally, the Agency is considering a rulemaking that would address transit roadway worker protections and operator assaults.

Maritime Administration

MARAD administers Federal laws and programs to improve and strengthen the
maritime transportation system to meet the economic, environmental, and security needs of the Nation. To that end, MARAD’s efforts are focused upon ensuring a strong American presence in the domestic and international trades and to expanding maritime opportunities for American businesses and workers.

MARAD’s regulatory objectives and priorities reflect the Agency’s responsibility for ensuring the availability of water transportation services for American shippers and consumers and, in times of war or national emergency, for the U.S. armed forces.

For Fiscal Year 2022, MARAD will continue its work increasing the efficiency of program operations by updating and clarifying implementing rules and program administrative procedures.

**Pipeline and Hazardous Materials Safety Administration**

PHMSA has responsibility for rulemaking focused on hazardous materials transportation and pipeline safety. In addition, PHMSA administers programs under the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990.

In Fiscal Year 2022, PHMSA will focus on the Gas Pipeline Leak Detection and Repair rulemaking, which would amend the Pipeline Safety Regulations to enhance requirements for detecting and repairing leaks on new and existing natural gas distribution, gas transmission, and gas gathering pipelines. PHMSA anticipates that the amendments proposed in this rulemaking would reduce methane emissions arising from avoidance/remediation of leaks and incidents from natural gas pipelines and address environmental justice concerns by improving the safety of natural gas pipelines near environmental justice communities and mitigating the risks for those communities arising from climate change.

PHMSA will also focus on the Improving the Safety of Transporting Liquefied Natural Gas rulemaking. This rulemaking action would amend the Hazardous Materials Regulations governing transportation of liquefied natural gas (LNG) in rail tank cars. This rulemaking action would incorporate the results of ongoing research efforts and collaboration with other Department of Transportation Operating Administrations and external technical experts; respond to a directive in Executive Order 13990 for PHMSA to review recent actions that could be obstacles to Administration policies promoting public health and safety, the environment, and climate change mitigation; and provide an opportunity for stakeholders and the public to contribute their perspectives on rail transportation of LNG.

**DOT—OFFICE OF THE SECRETARY (OST)**

**Proposed Rule Stage**

**129. +Processing Buy America and Buy American waivers based on Nonavailability**

- **Priority:** Other Significant.
- **CFR Citation:** Not Yet Determined.
- **Legal Deadline:** None.
- **Abstract:** This rule will establish the applicable regulatory standard for waivers from the Buy America requirement on the basis that a product or item is not manufactured in the United States meeting the applicable Buy America requirement. This standard will require the use of items and products with the maximum known amount of domestic content. The rule will also establish the required information, which is expected to be consistent across the Department, the applicants must provide in applying for such waivers.

- **Statement of Need:** Pursuant to Executive Order 13788, Buy American and Hire American, which establishes as a policy of the executive branch to “maximize, consistent with law . . . the use of goods, products, and materials produced in the United States,” DOT will be requiring that applicants for non-availability waivers select products that maximize domestic content. In addition, this rule will streamline the Buy America non-availability waiver process, and improve coordination across the Department of Transportation.

- **Alternatives:** TBD.
- **Anticipated Cost and Benefits:** TBD. Risks: TBD.
- **Timetable:**

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**DOT—OST**

**130. +Accessible Lavatories on Single-Aisle Aircraft: Part II**

- **Priority:** Other Significant. Major under 5 U.S.C. 801.
- **Legal Authority:** Air Carrier Access Act, 49 U.S.C. 41705
- **CFR Citation:** 14 CFR part 382.
- **Legal Deadline:** None.
- **Abstract:** This rulemaking proposes that airlines make lavatories on new single-aisle aircraft large enough, equivalent to that currently found on twin-aisle aircraft, to permit a passenger with a disability (with the help of an assistant, if necessary) to approach, enter, and maneuver within the aircraft lavatory as necessary to use all lavatory facilities and leave by means of the aircraft’s on-board wheelchair.

- **Statement of Need:** This rulemaking proposes to improve accessibility of lavatories on single-aisle aircraft.

- **Summary of Legal Basis:** 49 U.S.C. 41705; 14 CFR part 382.

- **Alternatives:** N/A.
- **Anticipated Cost and Benefits:** TBD. Risks: TBD.
- **Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** No.

**Small Entities Affected:** No.

**Government Levels Affected:** None. Federalism: Undetermined.

**URL For More Information:** www.regulations.gov.

**URL For Public Comments:** www.regulations.gov.

**Agency Contact:** Michael A. Smith, Attorney Advisor, Department of Transportation, Office of the Secretary, 1200 New Jersey Avenue SE, Washington, DC 20590, Phone: 202 366–4000, Email: michael.a.smith@dot.gov. RIN: 2105–AE79

**Agency Contact:** Blane A. Workie, Assistant General Counsel, Department of Transportation, Office of the Secretary, 1200 New Jersey Avenue SE,
DOT—OST
131. § +Enhancing Transparency of Airline Ancillary Service Fees

Priority: Other Significant.
Legal Authority: 49 U.S.C. 41712
CFR Citation: 14 CFR 399.
Legal Deadline: None.
The Department of Transportation is proposing to amend its aviation consumer protection regulations to ensure that consumers have ancillary fee information, including “baggage fees,” “change fees,” and “cancellation fees” at the time of ticket purchase. This rulemaking would also examine whether fees for certain ancillary services should be disclosed at the first point in a search process where a fare is listed. This rulemaking implements section 5, paragraph (m)(i)(F) of Executive Order 14.

Abstract: This rulemaking would amend DOT’s aviation consumer protection regulations to ensure that consumers have ancillary fee information, including “baggage fees,” “change fees,” and “cancellation fees” at the time of ticket purchase. This rulemaking would also examine whether fees for certain ancillary services should be disclosed at the first point in a search process where a fare is listed. This rulemaking implements section 5, paragraph (m)(i)(F) of Executive Order 14036 on Promoting Competition in the American Economy, which directs the Department to better protect consumers and improve competition.

Statement of Need: This rulemaking proposes that consumers have ancillary fee information, including “baggage fees,” “change fees,” and “cancellation fees,” at the time of ticket purchase.


Alternatives: N/A.
Anticipated Cost and Benefits: TBD.
Risks: N/A.
Timetable:

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Government Levels Affected: None.

DOT—FEDERAL AVIATION ADMINISTRATION (FAA)

Final Rule Stage

132. § Registration and Marking Requirements for Small Unmanned Aircraft

Priority: Other Significant.
Legal Authority: 49 U.S.C. 106(f), 49 U.S.C. 41703, 44101 to 44106, 44110 to 44113, and 44701
CFR Citation: 14 CFR 1; 14 CFR 375; 14 CFR 45; 14 CFR 47; 14 CFR 48; 14 CFR 91.
Legal Deadline: None.
Abstract: This rulemaking would provide an alternative, streamlined and simple, web-based aircraft registration process for the registration of small unmanned aircraft, including small unmanned aircraft operated exclusively for limited recreational operations, to facilitate compliance with the statutory requirement that all aircraft register prior to operation. It would also provide a simpler method for marking small unmanned aircraft that is more appropriate for these aircraft. This action responds to public comments received regarding the proposed registration process in the Operation and Certification of Small Unmanned Aircraft notice of proposed rulemaking, the request for information regarding unmanned aircraft system registration, and the recommendations from the Unmanned Aircraft System Registration Task Force.

Statement of Need: This interim final rule (IFR) provides an alternative process that small unmanned aircraft owners may use to comply with the statutory requirements for aircraft operations. As provided in the clarification of these statutory requirements and request for further information issued October 19, 2015, 49 U.S.C. 44102 requires aircraft to be registered prior to operation. See 80 FR 63912 (October 22, 2015). Currently, the only registration and aircraft identification process available to comply with the statutory aircraft registration requirement for all aircraft owners, including small unmanned aircraft, is the paper-based system set forth in 14 CFR parts 45 and 47. As the Secretary and the Administrator noted in the clarification issued October 19, 2015 and further analyzed in the regulatory evaluation accompanying this rulemaking, the Department and the FAA have determined that this process is too onerous for small unmanned aircraft owners and the FAA. Thus, after considering public comments and the recommendations from the Unmanned Aircraft System (UAS) Registration Task Force, the Department and the FAA have developed an alternative process, provided by this IFR (14 CFR part 48), for registration and marking available only to small unmanned aircraft owners. Small unmanned aircraft owners may use this process to comply with the statutory requirement to register their aircraft prior to operating in the National Airspace System (NAS).

Summary of Legal Basis: The FAA’s authority to issue rules on 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 49 U.S.C. 106(f), which establishes the authority of the Administrator to promulgate regulations and rules; and 49 U.S.C. 44701(a)(5), which requires the Administrator to promote safe flight of civil aircraft in air commerce by prescribing regulations and setting minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security. This rule is also promulgated pursuant to 49 U.S.C. 44101–44106 and 44110–44113 which require aircraft to be registered as a condition of operation and establish the requirements for registration and registration processes. Additionally, this rulemaking is promulgated pursuant to the Secretary’s authority in 49 U.S.C. 41703 to permit the operation of foreign civil aircraft in the United States.

Alternatives: Currently, the only registration and aircraft identification process available to comply with the statutory aircraft registration requirement for all aircraft owners, including small unmanned aircraft, is the paper-based system set forth in 14 CFR parts 45 and 47. As the Secretary and the Administrator noted in the clarification issued October 19, 2015 and further analyzed in the regulatory evaluation accompanying this rulemaking, the Department and the FAA have determined that this process
is too onerous for small unmanned aircraft owners and the FAA.

**Anticipated Cost and Benefits:** In order to implement the new streamlined, web-based system described in this interim final rule (IFR), the FAA will incur costs to develop, implement, and maintain the system. Small UAS owners will require time to register and mark their aircraft, and that time has a cost. The total of government and registrant resource cost for small unmanned aircraft registration and marking under this new system is $56 million ($46 million present value at 7 percent) through 2020. In evaluating the impact of this interim final rule, we compare the costs and benefits of the IFR to a baseline consistent with existing practices: For modelers, the exercise of discretion by FAA (not requiring registration) and continued broad public outreach and educational campaign, and for non-modelers, registration via part 47 in the paper-based system. Given the time to register aircraft under the paper-based system and the projected number of sUAS aircraft under the paper-based system. Required registration via part 47 in the paper-based system. Given the time to register aircraft under the paper-based system and the projected number of sUAS aircraft under the paper-based system, the FAA estimates the cost to the government and non-modelers would be about $383 million. The resulting cost savings to society from this IFR equals the cost of this baseline policy ($383 million) minus the cost of this IFR ($56 million), or about $327 million ($259 million in present value at a 7 percent discount rate). These cost savings are the net quantified benefits of this IFR.

**Risks:** Many of the owners of these new sUAS may have no prior aviation experience and have little or no understanding of the NAS, let alone knowledge of the safe operating requirements and additional authorities required to conduct certain operations. Aircraft registration provides an immediate and direct opportunity for the agency to engage and educate these new users prior to operating their unmanned aircraft and to hold them accountable for noncompliance with safe operating requirements, thereby mitigating the risk associated with the influx of operations. In light of the increasing reports and incidents of unsafe incidents, rapid proliferation of both commercial and model aircraft operators, and the resulting increased risk, the Department has determined it is contrary to the public interest to proceed with further notice and comment rulemaking regarding aircraft registration for small unmanned aircraft. To minimize risk to other users of the NAS and people and property on the ground, it is critical that the Department be able to link the expected number of new unmanned aircraft to their owners and educate these new owners prior to commencing operations.

**Timetable:**

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**Regulatory Flexibility Analysis Required:** Yes.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** None.

**International Impacts:** This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**URL For More Information:** www.regulations.gov.

**URL For Public Comments:** www.regulations.gov.

**Agency Contact:** Bonnie Lefko, Department of Transportation, Federal Aviation Administration, 6500 S MacArthur Boulevard, Registry Building 26, Room 118, Oklahoma City, OK 73169, Phone: 405 954–7461, Email: bonnie.lefko@faa.gov.

**RIN:** 2120–AK82

**DOT—FEDERAL HIGHWAY ADMINISTRATION (FHWA)**

**Proposed Rule Stage**

**133. +Greenhouse Gas Emissions Measure**

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Legal Authority:** 23 U.S.C. 150

**CPR Citation:** 23 CFR 490.

**Legal Deadline:** None.

**Abstract:** This rulemaking would establish a method for the measurement and reporting of greenhouse gas (GHG) emissions associated with on-road transportation under title 23 of the United States Code (U.S.C.). It is proposed as an addition to existing FHWA regulations that establish a set of performance measures for State departments of transportation (State DOTs) and metropolitan planning organizations (MPOs) to use pursuant to 23 U.S.C. 150(c) or other authorities. Statements of Need. The proposed national performance management measure responds to the climate crisis. Establishing a method for measuring and reporting greenhouse gas (GHG) emissions associated with transportation under title 23, United States Code, is necessary because the environmental sustainability, including the carbon footprint, of the transportation system is an important attribute of the system that States can use to assess the performance of the Interstate and non-Interstate National Highway System (NHS). Consistent measurement and reporting of GHG emissions from on-road mobile source emissions under the proposed rule would assist all levels of government and the public in making more informed choices about GHG emissions trends.

**Summary of Legal Basis:** FHWA has the legal authority to establish the proposed GHG emissions measure under 23 U.S.C. 150(c)(3), which calls for performance measures that the States can use to assess performance of the Interstate and non-Interstate NHS for purposes of carrying out the National Highway Performance Program (NHPP) under 23 U.S.C. 119. Specifically, FHWA interprets the performance of the Interstate System and the NHS under 23 U.S.C. 150(c)(3)(A)(ii)(IV)–(V) to include environmental performance, consistent with the national goals established under 23 U.S.C. 150(b). Other statutory provisions also support the proposed measure, including 23 U.S.C. 119 (NHPP) and 23 U.S.C. 101(b)(3)(C) (transportation policy), 134(a)(1) (transportation planning policy), 134(c)(1) (metropolitan planning), and 135(d)(1) and (d)(2) (statewide planning process and a performance-based approach).

**Alternatives:** FHWA is developing a proposed rule and will consider all available alternatives in the development of its proposal.

**Anticipated Cost and Benefits:** FHWA is preparing a regulatory analysis of the costs and benefits associated with the proposed rule. In the analysis, FHWA anticipates quantifying estimates where possible and qualitatively discussing costs and benefits that cannot be quantified.

**Risks:** FHWA is developing a proposed rule and will consider potential risks in the development of its proposal.

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**Regulatory Flexibility Analysis Required:** No.

**Small Entities Affected:** No.
**DOT—FHWA**

Final Rule Stage

134. +Manual on Uniform Traffic Control Devices for Streets and Highways

*Priority:* Other Significant.

*Legal Authority:* 23 U.S.C. 101(a), 104, 109(d), 114(a), 217, 315, and 402(a)

*CFR Citation:* 23 CFR 655.

*Legal Deadline:* None.

*Abstract:* This rulemaking would update the Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD) incorporated by reference at 23 CFR part 655. The new edition would update the technical provisions of the 2009 edition to reflect advances in technologies and operational practices that are not currently allowed in the MUTCD.

*Statement of Need:* Updates to the MUTCD are needed to update the technical provisions to reflect advances in technologies and operational practices, incorporate recent trends and innovations, and set the stage for automated driving systems as those continue to take shape. The proposed changes to the MUTCD would promote uniformity and incorporate technology advances in the traffic control device application. They ultimately would improve and encourage the safe and efficient utilization of roads that are open to public travel.

*Summary of Legal Basis:* FHWA proposed this rule under 23 U.S.C. 109(d), 315, and 402(a), which give the Secretary of Transportation the authority to promulgate uniform provisions to promote the safe and efficient utilization of the highways. The Secretary has delegated this authority to FHWA under 49 CFR 1.85.

*Alternatives:* FHWA continues to consider all available alternatives in this rulemaking as the Agency considers public comments received on the Notice of Proposed Amendments (NPA) to inform a final rule.

*Anticipated Cost and Benefits:* FHWA estimated the costs and potential benefits of the proposed changes to the MUTCD in an economic analysis. FHWA analyzed the expected compliance costs associated with 132 proposed substantive revisions. As summarized in the NPA, FHWA found that 8 of those substantive revisions have quantifiable economic impacts. FHWA quantified the total estimated cost of 3 substantive revisions for which costs can be quantified as $541,978 when discounted at 7 percent and $589,667 when discounted at 3 percent, measured in 2018 dollars. FHWA lacked information to estimate the cost of 5 substantive revisions but expects they will have net benefits based on per-unit or per-mile costs and benefits of the proposed revisions. FHWA will update the economic analysis to reflect the final rule, to be designated as the 11th edition of the MUTCD.

*Risks:* FHWA is continuing to consider potential risks as the Agency considers public comments received on the NPA to inform a final rule.

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<td>02/02/21</td>
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**Regulatory Flexibility Analysis**

*Required:* No.

*Small Entities Affected:* No.

*Government Levels Affected:* Federal, Local, State, Tribal.


*URL For Public Comments:* www.regulations.gov.

*Agency Contact:* Kevin Sylvester, Department of Transportation, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Phone: 202 366–2161, Email: kevin.sylvester@dot.gov.

*RIN:* 2125–AF85

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**DOT—NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION (NHTSA)**

Proposed Rule Stage

135. +Heavy Vehicle Automatic Emergency Braking


*CFR Citation:* 49 CFR 571.

*Legal Deadline:* None.

*Abstract:* This notice will seek comments on a proposal to require and/or standardize equipment performance for automatic emergency braking on heavy trucks. The agency previously published a notice (80 FR 62467) on October 16, 2015, granting a petition for rulemaking submitted by the Truck Safety Coalition, the Center for Auto Safety, Advocates for Highway and Auto Safety, and Road Safe America (dated February 19, 2015), to establish a safety standard to require automatic forward collision avoidance and mitigation (FCAM) systems on certain heavy vehicles. For several years, NHTSA has researched forward collision avoidance and mitigation technology on heavy vehicles, including forward collision warning and automatic emergency braking systems. This rulemaking proposes test procedures for measuring performance of these systems.

*Statement of Need:* This proposed rule would establish a safety standard to require and/or standardize performance of automatic forward collision avoidance and mitigation systems on heavy vehicles. NHTSA believes there is potential for AEB to improve safety by reducing the likelihood of rear-end crashes involving heavy vehicles and the severity of crashes. NHTSA is commencing the rulemaking process to potentially require new heavy vehicles to be equipped with automatic emergency braking systems, to standardize AEB performance when the systems are optionally installed on vehicles.


*Alternatives:* NHTSA will present regulatory alternatives in the NPRM.

*Anticipated Cost and Benefits:* NHTSA will present preliminary costs and benefits in the NPRM.

*Risks:* The agency believes there are no substantial risks to this rulemaking.

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**Regulatory Flexibility Analysis**

*Required:* No.

*Small Entities Affected:* No.

*Government Levels Affected:* None.


*URL For Public Comments:* www.regulations.gov.

*Agency Contact:* David Hines, Director, Office of Crash Avoidance
Standards, Department of Transportation, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Phone: 202–366–2720, Email: david.hines@dot.gov.
RIN: 2127–AM36

DOT—NHTSA

136. +Light Vehicle Automatic Emergency Braking (AEB) With Pedestrian AEB

CFR Citation: 49 CFR 571.
Legal Deadline: None.
Abstract: This notice will seek comment on a proposal to require and/or standardize performance for Light Vehicle Automatic Emergency Braking (AEB), including Pedestrian AEB (PAEB), on all newly manufactured light vehicles. A vehicle with AEB detects crash imminent situations in which the vehicle is moving forward towards another vehicle and/or a pedestrian, and automatically applies the brakes to prevent the crash from occurring, or to mitigate the severity of the crash. This rulemaking would set performance requirements and would specify a test procedure under which compliance with those requirements would be measured.
Statement of Need: This proposed rule would reduce rear end vehicle-to-vehicle crashes and could reduce motor vehicle impacts with pedestrians that often result in death and injury.
Summary of Legal Basis: 49 U.S.C. 322, 30111, 30115, 30117, 30166; delegation of authority at 49 CFR 1.95
Alternatives: NHTSA will present regulatory alternatives in the NPRM.
Anticipated Cost and Benefits: NHTSA will present preliminary costs and benefits in the NPRM.
Risks: The agency believes there are no substantial risks to this rulemaking.
Timetable:

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
URL For More Information: www.regulations.gov
URL For Public Comments: www.regulations.gov

DOT—NHTSA

137. +Corporate Average Fuel Economy (CAFE) Preemption

Priority: Other Significant. Legal Authority: delegation of authority at 49 CFR 1.95
CFR Citation: 49 CFR 533.
Legal Deadline: None.
Abstract: This action would repeal of The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, 84 FR 51310 (Sept. 27, 2019) (“SAFE 1 Rule”).
Statement of Need: This action is directed under Executive Order 13990.
Summary of Legal Basis: This rulemaking would respond to requirements of the Energy Independence and Security Act of 2007 (EISA), Title 1, Subtitle A, Section 102, as it amends 49 U.S.C. 32902. The statute requires that corporate average fuel economy standards be prescribed separately for passenger automobiles and non-passenger automobiles. For model years 2021 to 2030, the average fuel economy required to be attained by each fleet of passenger and non-passenger automobiles shall be the maximum feasible for each model year. The law requires the standards be set at least 18 months prior to the start of the model year.
Alternatives: NHTSA considered alternatives in its May 2021 NPRM. NHTSA will update the regulatory alternatives in the final rule as appropriate.
Anticipated Cost and Benefits: NHTSA estimated costs and benefits in its May 2021 NPRM. NHTSA will update the costs and benefits in the final rule as appropriate.
Risks: The agency believes there are no substantial risks to this rulemaking.
Timetable:

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<td>05/12/21</td>
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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
URL For More Information: www.regulations.gov

DOT—NHTSA

138. +Passenger Car and Light Truck Corporate Average Fuel Economy Standards

Legal Authority: Delegation of authority at 49 CFR 1.95
CFR Citation: 49 CFR 533.
Legal Deadline: None.
Abstract: This rulemaking would reconsider Corporate Average Fuel Economy (CAFE) standards for passenger cars and light trucks that were established in the agency’s April 30, 2020 final rule. This rulemaking would respond to requirements of the Energy Independence and Security Act of 2007 (EISA), Title 1, Subtitle A, Section 102, as it amends 49 U.S.C. 32902. The statute requires that corporate average fuel economy standards be prescribed separately for passenger automobiles and non-passenger automobiles. For model years 2021 to 2030, the average fuel economy required to be attained by each fleet of passenger and non-passenger automobiles shall be the maximum feasible for each model year. The law requires the standards be set at least 18 months prior to the start of the model year.
Statement of Need: This action is directed under Executive Order 13990.
Summary of Legal Basis: This rulemaking would respond to requirements of the Energy Independence and Security Act of 2007 (EISA), Title 1, Subtitle A, Section 102, as it amends 49 U.S.C. 32902. The statute requires that corporate average fuel economy standards be prescribed separately for passenger automobiles and non-passenger automobiles. For model years 2021 to 2030, the average fuel economy required to be attained by each fleet of passenger and non-passenger automobiles shall be the maximum feasible for each model year. The law requires the standards be set at least 18 months prior to the start of the model year.
Alternatives: NHTSA considered alternatives in its September 2021 NPRM. NHTSA will update the regulatory alternatives in the final rule as appropriate.
Anticipated Cost and Benefits: NHTSA estimated costs and benefits in...
its September 2021 NPRM. NHTSA will update the costs and benefits in the final rule as appropriate.

Risks: The agency believes there are no substantial risks to this rulemaking.  

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<td>86 FR 49602</td>
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Regulatory Flexibility Analysis  
Required: No.  
Small Entities Affected: No.  
Government Levels Affected: None.  
URL For Public Comments: www.regulations.gov.  
Agency Contact: Gregory Powell, Program Analyst, Department of Transportation, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Phone: 202 366–5206, Email: gregory.powell@dot.gov.  
RIN: 2127–AM34

DOT—FEDERAL RAILROAD ADMINISTRATION (FRA)  
Proposed Rule Stage

139. +Train Crew Staffing  
Priority: Other Significant.  
Legal Authority: 49 CFR 1.89(a); 49 U.S.C. 20103  
CFR Citation: 49 CFR 218.  
Legal Deadline: None.  
Abstract: This rulemaking would address the potential safety impact of one-person train operations, including appropriate measures to mitigate an accident’s impact and severity, and the patchwork of State laws concerning minimum crew staffing requirements. This rulemaking would address the issue of minimum requirements for the size of different train crew staffs, depending on the type of operations.  
Statement of Need: To address the potential safety impact of one-person train operations, including appropriate measures to mitigate an accident’s impact and severity, and the patchwork of State laws concerning minimum crew staffing requirements, FRA is drafting an NPRM that would address the issue of minimum requirements for the size of different train crew staffs, depending on the type of operation.  
Alternatives: FRA will analyze regulatory alternatives in the NPRM.  
Anticipated Cost and Benefits: FRA is currently expecting the economic impact of this rule is expected to be less than $100 million; however, FRA has not yet quantified the costs or benefits associated with this proposed rulemaking.  
Risks: The NPRM is based off a risk assessment that individual railroads will have to perform. The risks should be negatively impacted.  
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Regulatory Flexibility Analysis  
Required: Yes.  
Small Entities Affected: Businesses.  
Government Levels Affected: Local, State.  
URL For Public Comments: www.regulations.gov.  
Agency Contact: Amanda Maizel, Attorney Adviser, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Phone: 202 493–8014, Email: amanda.maizel@dot.gov.  
RIN: 2130–AC88

DOT—PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION (PHMSA)  
Long-Term Actions

140. +Pipeline Safety: Class Location Requirements  
Legal Authority: 49 U.S.C. 60101 et seq.  
CFR Citation: 49 CFR 192.  
Legal Deadline: None.  
Abstract: This rulemaking action would address class location requirements for natural gas transmission pipelines, specifically as they pertain to actions operators are required to take following class location changes due to population growth near the pipeline. Operators have suggested that performing integrity management measures on pipelines where class locations have changed due to population increases would be an equally safe but less costly alternative to the current class location change requirements. PHMSA is proposing revisions to the Federal Pipeline Safety Regulations to amend the requirements for pipelines that experience a change in class location. This proposed rule addresses a part of a congressional mandate from the Pipeline Safety Act of 2011 and responds to public input received as part of the rulemaking process. The amendments in this proposed rule would add an alternative set of requirements operators could use, based on implementing integrity management principles and pipe eligibility criteria, to manage certain pipeline segments where the class location has changed from a Class 1 location to a Class 3 location. PHMSA intends for this alternative to provide equivalent public safety in a more cost-effective manner to the current natural gas pipeline safety rules, which require operators to either reduce the pressure of the pipeline, pressure test the pipeline segment to higher standards, or replace the pipeline segment.  
Summary of Legal Basis: Congress established the current framework for regulating the safety of natural gas pipelines in the Natural Gas Pipeline Safety Act of 1968 (NGPSA). The NGPSA provided the Secretary of Transportation the authority to prescribe minimum Federal safety standards for natural gas pipeline facilities. That authority, as amended in subsequent reauthorizations, is currently codified in the Pipeline Safety Laws (49 U.S.C. 60101 et seq.).  
Alternatives: PHMSA is evaluating and considering additional regulatory alternatives to these proposed requirements, including a “no action” alternative.  
Anticipated Cost and Benefits: Estimated annual cost savings are $149 million.
Risks: The alternative conditions
PHMSA is proposing to allow operators to manage class location changes through IM will provide an equivalent level of safety as the existing class location change regulations.

Timetable:

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<td>83 FR 36861</td>
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<td>85 FR 65142</td>
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Regulatory Flexibility Analysis
Required: Undetermined.
Government Levels Affected: None.
URL For Public Comments: www.regulations.gov.
Agency Contact: Cameron H. Satterthwaite, Transportation Regulations Specialist, Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Phone: 202–366–8553, Email: cameron.satterthwaite@dot.gov.
RIN: 2137–AF29
BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY
Statement of Regulatory Priorities

The primary mission of the Department of the Treasury is to maintain a strong economy and create economic and job opportunities by promoting the conditions that enable economic growth and stability at home and abroad, strengthen national security by combatting threats and protecting the integrity of the financial system, and manage the U.S. Government’s finances and resources effectively.

Consistent with this mission, regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by Congress and signed by the President. It is the policy of the Department to comply with applicable requirements to issue a Notice of Proposed Rulemaking and carefully consider public comments before adopting a final rule. Also, the Department invites interested parties to submit views on rulemaking projects while a proposed rule is being developed.

To the extent permitted by law, it is the policy of the Department to adhere to the regulatory philosophy and principles set forth in Executive Orders 12866, 13563, and 13609 and to develop regulations that maximize aggregate net benefits to society while minimizing the economic and paperwork burdens imposed on persons and businesses subject to those regulations.

Alcohol and Tobacco Tax and Trade Bureau

The Alcohol and Tobacco Tax and Trade Bureau (TTB) issues regulations to implement and enforce federal laws relating to alcohol, tobacco, firearms, and ammunition excise taxes and certain non-tax laws relating to alcohol. TTB’s mission and regulations are designed to:

1. Collect the taxes on alcohol, tobacco products, firearms, and ammunition;
2. Protect the consumer by ensuring the integrity of alcohol products;
3. Ensure only qualified businesses enter the alcohol and tobacco industries; and
4. Prevent unfair and unlawful market activity for alcohol and tobacco products.

In FY 2022, TTB will continue its multi-year Regulations Modernization effort by prioritizing projects that reduce regulatory burdens, streamline and simplify requirements, and improve service to regulated businesses. Specifically, TTB plans to publish deregulatory rules that will reduce the amount of information industry members must submit to TTB in connection with permit and similar applications to engage in regulated businesses, and reduce the types of operational activities that require prior approval. TTB expects these proposals to ultimately reduce the amount of operational information industry members must submit to TTB and provide for the piloting of a combined tax return and simplified operations report, reducing the overall number of reports submitted. These measures are expected to reduce burden on industry members and provide them greater flexibility, and make starting new businesses easier and faster for new industry members.

TTB will also prioritize rulemaking to amend its regulations to reflect statutory changes pursuant to the Taxpayer Certainty and Disaster Tax Act of 2020, which made permanent most of the Craft Beverage Modernization and Tax Reform provisions of the Tax Cuts and Jobs Act of 2017. These legislative changes included reduced tax rates for beer and distilled spirits and tax credits for wineries and other producers that had previously been provided on a temporary basis, as well as new provisions on the types of activities that qualify for reduced tax rates for distilled spirits and on permissible transfers of bottled distilled spirits in bond.

Additionally, as a result of this legislation, and as addressed in a June 2021 Report to Congress on Administration of Craft Beverage Modernization Act Refund Claims for Imported Alcohol, TTB will also prioritize rulemaking to implement and administer refund claims for imported alcohol.

Additional priority projects include rulemaking to authorize new container sizes (standards of fill) for wine and responding to industry member petitions to authorize new wine treating materials and processes, new grape varietal names for use on labels of wine, and new American Viticultural Areas (AVAs).

This fiscal year TTB plans to prioritize the following measures:

- Streamlining and Modernizing the Permit Application Process (RIN: 1513–AC46, 1513–AC47, and 1513–AC48)
- Modernization of Permit and Registration Application Requirements for Distilled Spirits Plants, Permit Applications for Wineries, and Qualification Requirements for Brewers, respectively.

In FY 2017, TTB engaged in a review of its regulations to identify any regulatory requirements that could potentially be eliminated, modified, or streamlined to reduce burdens on industry related to application and qualification requirements. Since that time, TTB has removed a number of requirements, particularly with regard to the information that is required to be submitted on TTB permit-related forms.

In FY 2022, TTB intends to propose amendments to its regulations to further streamline the qualification and application requirements for new and existing businesses, including distilled spirits plants, wineries, and breweries.


In FY 2022, TTB intends to propose for notice and comment regulatory amendments to substantially streamline current requirements pertaining to tax returns and operational reports and reducing the amount of information and the number of reports submitted. This measure will also include updates to return and report requirements to improve overall tax oversight and enforcement.

- Modernizing the Alcohol Beverage Labeling and Advertising Requirements (RIN: 1513–AC66, Modernization of the Labeling and Advertising Requirements for Distilled Spirits and Malt Beverage, and RIN: 1513–AC67, Modernization of
The Federal Alcohol Administration Act requires that alcohol beverages introduced in interstate commerce have a label approved under regulations prescribed by the Secretary of the Treasury. TTB conducted an analysis of its alcohol beverage labeling regulations to identify any that might be outdated, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with that analysis. These regulations were also reviewed to assess their applicability to the modern alcohol beverage marketplace. As a result of this review, in FY 2019, TTB proposed revisions to the regulations concerning the labeling requirements for wine, distilled spirits, and malt beverages. TTB anticipated that these regulatory changes would assist industry in voluntary compliance, decrease industry burden, and result in the regulated industries being able to bring products to market without undue delay. TTB received over 1,100 comments in response to the notice, which included suggestions for further revisions. In FY 2020, TTB published in the Federal Register (85 FR 18704) a final rule amending its regulations to make permanent certain of the proposed liberalizing and clarifying changes, and to provide certainty with regard to certain other proposals that commenters generally opposed and that TTB did not intend to adopt. In FY 2022, TTB intends to address remaining aspects of this rulemaking initiative, including incorporating a proposed reorganization of the regulatory provisions intended to make the regulations easier to read and understand, for which industry members expressed support.


TTB is amending its regulations for beer, wine, and distilled spirits, including those related to administration of import claims, to implement changes made to the Internal Revenue Code by the Taxpayer Certainty and Disaster Act of 2020, which made permanent most of the Craft Beverage Modernization and Tax Reform (CBMA) provisions of the Tax Cuts and Jobs Act of 2017. The CBMA provisions reduced excise taxes on all beverage alcohol producers, large and small, foreign and domestic. In 2020, these tax cuts were made permanent. The 2020 provisions also transferred responsibility for administering certain CBMA provisions for imported alcohol from U.S. Customs and Border Protection (CBP) to the Treasury Department after December 31, 2022. Importers will be required to pay the full tax rate at entry and submit refund claims to Treasury. Treasury intends for TTB to administer these claims.

- **Authorizing the Use of Additional Wine Treating Materials and Soliciting Comments on Proposed Changes to the Limits on the Use of Wine Treating Materials to Reflect “Good Manufacturing Practice” (RIN: 1513–AB61 and 1513–AC75)**

In FY 2017, TTB proposed to amend its regulations pertaining to the production of wine to authorize additional treatments that may be applied to wine and to juice from which wine is made. These proposed amendments were made in response to requests from wine industry members to authorize certain wine treating materials and processes not currently authorized by TTB regulations. Although TTB may administratively approve such treatments, such administrative approval does not guarantee acceptance in foreign markets of any wine so treated. Under certain international agreements, wine made with wine treating materials is not subject to certain restrictions if the authorization to use the treating materials is implemented through public notice; thus, rulemaking facilitates the acceptance of exported wine made using those treatments in foreign markets. In FY 2018, TTB reopened the comment period for the notice in response to industry member requests and, after consideration of the comments, TTB intends in FY 2022 to issue a final rule on those proposals. In FY 2022, TTB also intends to propose for public comment additional changes to the regulations governing wine treating materials, in response to a petition to more broadly amend the regulations to allow more wine treating materials to be used within the limitations of “good manufacturing practice” rather than within specified numerical limits.

- **Addition of New Standards of Fill for Wine (RIN: 1513–AC86)**

TTB plans to publish a proposal to amend the regulations governing wine containers to add additional authorized standards of fill in response to requests it has received for such standards, and to be consistent with a Side Letter included as part of a U.S.–Japan Trade Agreement that addresses issues related to market access and, specifically, to alcohol beverage standards of fill. TTB will also propose a technical amendment to add equivalent standard United States measures to the wine labeling regulations for recently approved wine standards of fill and for the additional sizes proposed in this notice.

- **Addition of Singani to the Standards of Identity for Distilled Spirits (RIN: 1513–AC61)**

On August 25, 2021, TTB published a proposal (86 FR 47429) to amend the regulations that set forth the standards of identity for distilled spirits to include Singani as a type of brandy that is a distinctive product of Bolivia. This proposal follows a joint petition submitted by the Plurinational State of Bolivia and Singani 63, Inc., and subsequent discussions with the Office of the United States Trade Representative. TTB solicited comments on this proposal, including comments on its proposal to authorize a minimum bottling proof of 35 percent alcohol by volume (or 70° proof) for Singani. TTB expects to publish a final rule in FY22.

- **Proposal to Amend the Regulations to Add New Grape Variety Names for American Wines (RIN: 1513–AC24)**

In FY 2017, TTB proposed to amend its wine labeling regulations by adding a number of new names to the list of grape variety names approved for use in designating American wines. The proposed deregulatory amendments would allow wine bottlers to use these additional approved grape variety names on wine labels and in wine advertisements in the U.S. and international markets. In 2018, TTB reopened the comment period for the notice in response to the agency’s inability to complete this project in FY 2020 because of redirected efforts to address COVID–19 guidance, and TTB now intends to issue a final rule in FY 2022.

**Office of the Comptroller of the Currency**

The Office of the Comptroller of the Currency (OCC) charters, regulates, and supervises all national banks and Federal savings associations (FSAs). The agency also supervises the Federal branches and agencies of foreign banks. The OCC’s mission is to ensure that national banks and FSAs operate in a safe and sound manner, provide fair access to financial services, treat customers fairly, and comply with applicable laws and regulations. Regulatory priorities for fiscal year 2022 are described below.

- **Amendments to Bank Secrecy Act Compliance Program Rule (12 CFR part 21)**

The OCC, the Board of Governors of the Federal Reserve System (FRB), and
the Federal Deposit Insurance Corporation (FDIC) plan to issue a notice of proposed rulemaking amending their respective Bank Secrecy Act Compliance Program Rules.

- **Basel III Revisions (12 CFR part 3).** The OCC, the FRB, and the FDIC plan to issue a notice of proposed rulemaking that would comprehensively revise the agencies’ risk-based capital rules, including revisions to the current standardized and advanced approaches capital rules.

- **Capital Requirements for Market Risk: Fundamental Review of the Trading Book (12 CFR part 3).** The OCC, the FRB, and the FDIC plan to issue a notice of proposed rulemaking to revise their respective capital requirements for market risk, which are generally applied to banking organizations with substantial trading activity. The banking agencies expect the proposal to be generally consistent with the standards set forth in the Fundamental Review of the Trading Book published by the Basel Committee on Bank Supervision.

- **Community Reinvestment Act Regulations (12 CFR parts 25 and 195).** The OCC plans to issue a proposal to replace the current Community Reinvestment Act (CRA) rule with revised rules largely based on the 1995 CRA regulations.

- **Community Reinvestment Act Regulations (12 CFR part 25).** Along with the Federal Deposit Insurance Agency and the Board of Governors of the Federal Reserve, the OCC plans to issue a joint rule to modernize the Community Reinvestment Act regulations.

- **Computer-Security Incident Notification (12 CFR part 53).** The OCC, FRB, and FDIC plan to issue a final rule that would require a banking organization to notify its primary federal regulator of significant computer-security incidents on a timely basis. The rule would also require a bank service provider to promptly notify banking organization customers of certain significant computer-security incidents. The notice of proposed rulemaking was published on January 12, 2021 (86 FR 2299).

- **Exemptions to Suspicious Activity Report Requirements (12 CFR parts 21 and 163).** The OCC plans to issue a final rule to modify the requirements for national banks and Federal savings associations to file Suspicious Activity Reports. The rule would amend the OCC’s Suspicious Activity Report regulations to allow the OCC to grant relief to national banks or federal savings associations that develop innovative solutions to meet Bank Secrecy Act requirements more efficiently and effectively. The notice of proposed rulemaking was published on January 22, 2021 (86 FR 6572).

- **Implementation of Emergency Capital Investment Program (12 CFR part 3).** Section 104A of the Community Development Banking and Financial Institutions Act of 1994, which was added by the Consolidated Appropriations Act, 2021, authorizes the Secretary of the Treasury to establish the Emergency Capital Investment Program (ECIP) through which the Department of the Treasury (Treasury) can make capital investments in low- and moderate-income community financial institutions. The purpose of ECIP is to support the efforts of such financial institutions to, among other things, provide financial intermediary services for small businesses, minority-owned businesses, and consumers, especially in low-income and underserved communities. In order to support and facilitate the timely implementation and acceptance of ECIP and promote its purpose, the OCC, FRB, and FDIC plan to issue a final rule that provides that preferred stock issued to Treasury under ECIP qualifies as additional tier 1 capital and that subordinated debt issued to Treasury under ECIP qualifies as tier 2 capital under the agencies’ capital rule. The interim final rule was published on March 22, 2021 (86 FR 15076).

- **Rules of Practice and Procedure (12 CFR part 19).** The OCC, FRB, and FDIC plan to issue a proposed rule to amend their rules of practice and procedure to reflect modern filing and communication methods and improve or clarify other procedures.

- **Tax Allocation Agreements (12 CFR part 30).** The OCC, FRB, and FDIC plan to issue a final rule requiring banks that file income taxes as part of a consolidated group to develop and maintain tax allocation agreements with other members of the consolidated group. The notice of proposed rulemaking was published on May 10, 2021 (86 FR 24755).

### Customs Revenue Functions

The Homeland Security Act of 2002 (the Act) provides that, although many functions of the former United States Customs Service were transferred to the Department of Homeland Security, the Secretary of the Treasury retains sole legal authority over customs revenue functions. The Act also authorize the Secretary of the Treasury to delegate any of the retained authority over customs revenue functions to the Secretary of Homeland Security. By Treasury Department Order No. 100–16, the Secretary of the Treasury delegated to the Secretary of Homeland Security authority to prescribe regulations pertaining to the customs revenue functions subject to certain exceptions, but further provided that the Secretary of the Treasury retained the sole authority to approve such regulations. During fiscal year 2021, CBP and Treasury plan to give priority to regulatory matters involving the customs revenue functions which streamline CBP procedures, protect the public, or are required by either statute or Executive Order. Examples of these efforts are described below.

- **Investigation of Claims of Evasion of Antidumping and Countervailing Duties.** The Treasury and CBP plan to finalize interim regulations (81 FR 56477) which amended CBP regulations implementing section 421 of the Trade Facilitation and Trade Enforcement Act of 2015, which set forth procedures to investigate claims of evasion of antidumping and countervailing duty orders.

- **Enforcement of Copyrights and the Digital Millennium Copyright Act.** The Treasury and CBP plan to finalize proposed amendments to the CBP regulations pertaining to importations of merchandise that violate or are suspected of violating the copyright laws, including the Digital Millennium Copyright Act (DMCA), in accordance with Title III of the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA) and Executive Order 13785, “Establishing Enhanced Collection and Enforcement of Anti-dumping and Countervailing Duties and Violations of Trade and Customs Laws.” The proposed amendments are intended to enhance CBP’s enforcement efforts against increasingly sophisticated piratical goods, clarify the definition of piracy, simplify the detention process relative to goods suspected of violating the copyright laws, and prescribe new regulations enforcing the DMCA.

- **Inter Partes Proceedings Concerning Exclusion Orders Based on Unfair Practices in Import Trade.** The Treasury and CBP plan to publish a proposal to amend its regulations with respect to administrative rulings related to the importation of articles in light of exclusion orders issued by the United States International Trade Commission (“Commission”) under section 337 of the Tariff Act of 1930, as amended. The proposed amendments seek to promote
the speed, accuracy, and transparency of such rulings through the creation of an inter partes proceeding to replace the current ex parte process.

- **Merchandise Produced by Convict or Forced Labor or Indentured Labor under Penal Sanctions.**

Treasury and CBP plan to publish a proposed rule to update, modernize, and streamline the process for enforcing the prohibition in 19 U.S.C. 1307 against the importation of merchandise that has been mined, produced, or manufactured, wholly or in part, in any foreign country by convict labor, forced labor, or indentured labor under penal sanctions. The proposed rule would generally bring the forced labor regulations and detention procedures into alignment with other statutes, regulations, and procedures that apply to the enforcement of restrictions against other types of prohibited merchandise.

- **Non-Preferential Origin Determinations for Merchandise Imported From Canada or Mexico for Implementation of the Agreement Between the United States of America, the United Mexican States, and Canada (USMCA).**

Treasury and CBP plan to finalize a proposed rule to harmonize non-preferential origin determinations for merchandise imported from Canada or Mexico. Such determinations would be made using certain tariff-based rules of origin to determine when a good imported from Canada or Mexico has been substantially transformed resulting in an article with a new name, character, or use. Once finalized, the rule is intended to reduce administrative burdens and inconsistency for non-preferential origin determinations for merchandise imported from Canada or Mexico for purposes of the implementation of the USMCA.

**Financial Crimes Enforcement Network**

As administrator of the Bank Secrecy Act (BSA), the Financial Crimes Enforcement Network (FinCEN) is responsible for developing and implementing regulations that are the core of the Department’s anti-money laundering (AML) and countering the financing of terrorism (CFT) efforts. FinCEN’s responsibilities and objectives are linked to, and flow from, that role. In fulfilling this role, FinCEN seeks to enhance U.S. national security by making the financial system increasingly resistant to abuse by money launderers, terrorists and their financial supporters, and other perpetrators of crime.

The Secretary of the Treasury, through FinCEN, is authorized by the BSA to issue regulations requiring financial institutions to file reports and keep records that are highly useful in criminal, tax, or regulatory investigations, risk assessments, or proceedings, or intelligence or counter-intelligence activities, including analysis, to protect against terrorism. The BSA also authorizes FinCEN to require that designated financial institutions establish AML/CFT programs and compliance procedures. To implement and realize its mission, FinCEN has established regulatory objectives and priorities to safeguard the financial system from the abuses of financial crime, including terrorist financing, proliferation financing, money laundering, and other illicit activity.

These objectives and priorities include: (1) Issuing, interpreting, and enforcing compliance with regulations implementing the BSA; (2) supporting, working with, and as appropriate overseeing compliance examination functions delegated by FinCEN to other Federal regulators; (3) managing the collection, processing, storage, and dissemination of data related to the BSA; (4) maintaining a government-wide access service to that same data for authorized users with a range of interests; (5) conducting analysis in support of policymakers, law enforcement, regulatory and intelligence agencies, and (for compliance purposes) the financial sector; and (6) coordinating with and collaborating on AML/CFT initiatives with domestic law enforcement and intelligence agencies, as well as foreign financial intelligence units.

FinCEN’s regulatory priorities for fiscal year 2022 include:

- Section 6110. BSA Application to Dealers in Antiquities and Assessment of BSA Application to Dealers in Art. On September 24, 2021, FinCEN issued an Advance Notice of Proposed Rulemaking (ANPRM) in order to implement Section 6110 of the Anti-Money Laundering Act of 2020 (the AML Act). This section amends the BSA (31 U.S.C. 5312(a)(2)) to include as a financial institution a person engaged in the trade of antiquities, including an advisor, consultant, or any other person who engages as a business in the solicitation or the sale of antiquities, subject to regulations prescribed by the Secretary of the Treasury. The section further requires the Secretary of the Treasury to issue proposed rules to implement the amendment within 360 days of enactment of the AML Act.

- Reports of Foreign Financial Accounts Civil Penalties (Technical Change). FinCEN is amending 31 CFR 1010.820 to withdraw the reports of foreign financial accounts (FBAR) civil monetary penalties language at 31 CFR 1010.820(g), which was made obsolete with the enactment of the American Jobs Creation Act of 2004. The American Jobs Creation Act of 2004 amended 31 U.S.C. 5321(a)(5) to allow for a greater maximum penalty for a willful violation of 31 U.S.C. 5314 than was previously authorized.

- Clarification of the requirement to collect, retain, and transmit information on transactions involving convertible virtual currency and digital assets with legal tender status.

The Board of Governors of the Federal Reserve System and FinCEN (collectively, the “Agencies”) intend to issue a revised proposal to clarify the meaning of “money” as used in the rules implementing the BSA requiring financial institutions to collect, retain, and transmit information on certain funds transfers and transmittals of funds. The Agencies intend that the revised proposal will ensure that the rules apply to domestic and cross-border transactions involving convertible virtual currency, which is a medium of exchange (such as cryptocurrency) that either has an equivalent value as currency, or acts as a substitute for currency, but lacks legal tender status. The Agencies further intend that the revised proposal will clarify that these rules apply to domestic and cross-border transactions involving digital assets that have legal tender status.

- Real Estate Transaction Reports and Records. FinCEN will issue an Advanced Notice of Proposed Rulemaking (ANPRM) to seek guidance on a future rulemaking that would require certain legal entities involved in real estate transactions to submit reports and keep records. Specifically, the ANPRM will seek comment to assess if FinCEN in preparing a proposed rule that would potentially impose nationwide recordkeeping and reporting requirements on financial institutions and nonfinancial trades and businesses participating in purchases of real estate by certain legal entities that are not financed by a loan, mortgage, or other similar instrument.

- Section 6212. Pilot Program on Sharing Information Related to Suspicious Activity Reports (SARs) Within a Financial Group. FinCEN intends to issue a Notice of Proposed Rulemaking (NPRM) in order
to implement Section 6212 of the AML Act. This section amends the BSA (31 U.S.C. 5318(g)) to establish a pilot program that permits financial institutions to SAR information with their foreign branches, subsidiaries, and affiliates for the purpose of combating illicit finance risks. The section further requires the Secretary of the Treasury to issue rules to implement the amendment within one year of enactment of the AML Act.

- **Section 6101. Establishment of National Exam and Supervision Priorities.**

  FinCEN intends to issue a NPRM to implement Section 6101 of the AML Act. That section, among other things, amends section 5318(h) to title 31 of the United States Code to: (1) Require financial institutions to establish CFT programs in addition to AML programs; (2) require FinCEN to establish national AML/CFT Priorities and, as appropriate, promulgate implementing regulations within 180 days of the issuance of those priorities; and (3) provide that the duty to establish, maintain, and enforce a BSA AML/CFT program remains the responsibility of, and must be performed by, persons in the United States who are accessible to, and subject to oversight and supervision by, the Secretary of the Treasury and the appropriate Federal functional regulator. Additionally, FinCEN intends to propose other changes, including regulatory amendments to establish that all financial institutions subject to an AML/CFT program requirement must maintain a risk- and reasonably designed AML/CFT program, and that such a program must include a risk assessment process.

- **Sec. 6305. No Action Letter Program.**

  FinCEN will issue an ANPRM following the implementation of Section 6305 of the AML Act. This section required FinCEN to conduct an assessment on whether to issue no-action letters in response to specific conduct requests from third parties, and propose rulemaking if appropriate. The assessment concluded that FinCEN should issue no-action letters, subject to sufficient resources, and proposed rulemaking to follow the issuance of the report. The ANPRM will seek guidance on the contours of a FinCEN no-action letter process, and, if necessary and appropriate, may be followed by a NPRM establishing regulations to govern the process. The ANPRM will also solicit feedback on FinCEN’s current forms of regulatory guidance and rulemaking.

- **Voluntary Information Sharing Among Financial Institutions Under Section 314(b) of the USA PATRIOT Act.**

  FinCEN is considering issuing this rule to strengthen the administration of the regulation implementing the statutory safe harbor that allows eligible financial institutions and associations of financial institutions to voluntarily share information regarding activities that may involve terrorist acts or money laundering.

  - **Sec. 6314. Updating Whistleblower Incentives and Protection.**

    FinCEN intends to issue a NPRM relating to Section 6314 of the AML Act. Section 6314 of AML Act amends Section 5323 of title 31, United States Code. Section 6314, enacted on January 1, 2021, established a whistleblower program that requires FinCEN to pay an award, under regulations prescribed by FinCEN and subject to certain limitations, to eligible whistleblowers who voluntarily provide FinCEN or the Department of Justice (DOJ) with original information of a violation of the Bank Secrecy Act that leads to the successful enforcement of a covered judicial or administrative action, or related action, and requires that FinCEN preserve the confidentiality of a whistleblower.

  Additionally, section 6314 of the AML Act repealed 31 U.S.C. 5328, the previous whistleblower protection provision, and replaced it with a new subsection to 31 U.S.C. 5323: Subsection (g) “Protection of Whistleblowers.” The new subsection (g) prohibits retaliation by employers against individuals that provide FinCEN or the DOJ with information about potential Bank Secrecy Act violations; any individual alleging retaliation may seek relief by filing a complaint with the Department of Labor.

- **Section 6403. Corporate Transparency Act.**

  On April 5, 2021, FinCEN issued an ANPRM entitled “Beneficial Ownership Information Reporting Requirements,” relating to the Corporate Transparency Act (Sections 6401–6403 of the AML Act), and intends to issue a NPRM. Section 6403 of the AML Act amends the BSA by adding new Section 5336 to title 31 of the United States Code. New Section 5336 requires FinCEN to issue rules requiring: (i) Reporting companies, including those that provide FinCEN with information that identified by FinCEN. FInCEN is proposing to amend the regulations implementing the BSA to require banks and money service businesses to submit reports, keep records, and verify the identity of customers in relation to transactions involving convertible virtual currency (CVC) or digital assets with legal tender status (“legal tender digital assets” or “LTDA”) held in unhosted wallets, or held in wallets hosted in a jurisdiction identified by FinCEN.


  FinCEN is proposing to amend the regulations implementing the BSA regarding reports of foreign financial accounts (FBARs). The proposed changes are intended to clarify which persons will be required to file reports of foreign financial accounts and what information is reportable. The proposed changes are intended to amend two provisions of the FBAR regulation: (1) Signature or other authority; and (2) special rules. Treasury is considering whether the relevant statutory objectives can be achieved at a lower cost.

- **Withdraw Obligation to Civil Money Penalty Provisions for BSA Violations. (Technical Change)**
FinCEN is amending 31 CFR 1010.820 to withdraw the civil money penalty provisions for BSA violations that are obsolete. Statutory amendments have been made to specific civil BSA penalties since the regulation was last revised. In addition, the Federal Civil Penalties Inflation Adjustment Act of 1990 as amended, 28 U.S.C. 2461 note, requires agencies to issue regulations making annual adjustments reflecting the effect of inflation for civil penalties expressed in terms of a dollar amount. Those inflation adjustments are correctly captured in a separate regulation, and therefore the obsolete and inconsistent provisions will be withdrawn.

- Amendments to the Definitions of Broker or Dealer in Securities.
  FinCEN is finalizing amendments to the regulatory definitions of “broker or dealer in securities” under the regulations implementing the BSA.
  The changes are intended to expand the current scope of the definitions to include funding portals. In addition, these amendments would require funding portals to implement policies and procedures reasonably designed to achieve compliance with all of the BSA requirements that are currently applicable to brokers or dealers in securities.
  The rule to require these organizations to comply with the BSA regulations is intended to help prevent money laundering, terrorist financing, and other financial crimes.

- Other Requirements.
  FinCEN also will continue to issue proposed and final rules pursuant to section 311 of the USA PATRIOT Act, as appropriate. Finally, FinCEN expects that it may propose various technical and other regulatory amendments in conjunction with ongoing efforts with a comprehensive review of existing regulations to enhance regulatory efficiency required by Section 6216 of the AML Act.

**Bureau of the Fiscal Service**

The Bureau of the Fiscal Service (Fiscal Service) administers regulations pertaining to the Government’s financial activities, including: (1) Implementing Treasury’s borrowing authority, including regulating the sale and issue of Treasury securities; (2) administering Government revenue and debt collection; (3) administering government-wide accounting programs; (4) managing certain Federal investments; (5) disbursing the majority of Government electronic and check payments; (6) assisting Federal agencies in reducing the number of improper payments; and (7) providing administrative and operational support to Federal agencies through franchise shared services.

During fiscal year 2022, Fiscal Service will accord priority to the following regulatory projects:

- **Surety Companies Doing Business with the United States.**
  Fiscal Service is proposing to amend its regulations governing surety companies doing business with the United States, found at 31 CFR part 223. When a federal law requires a person to post a bond through a surety, the person satisfies the requirement if the bond is underwritten by a company that is certified by Treasury to write federal bonds. Fiscal Service administers the regulations governing the issuance, renewal, and revocation of certificates of authority to surety companies to write or reinsure federal bonds. Fiscal Service proposes to amend its regulations governing how it values the assets and liabilities of sureties to keep pace with changes in regulation of the surety industry occurring at the state and international levels.

- **Government Participation in the Automated Clearing House.**
  The Fiscal Service is proposing to amend its regulation at 31 CFR part 210 governing the government’s participation in the Automated Clearing House (ACH). The proposed amendment would address changes to the National Automated Clearing House Association’s (Nacha) private-sector ACH rules that have been adopted since those rules were last incorporated by reference in part 210. Among other things, the amendment would address the increase in the Same-Day ACH transaction limit from $100,000 per transaction to $1,000,000 per transaction.

- **Re-Write of DCIA Offset Regulations in 31 CFR part 285 subpart A.**
  The Fiscal Service is proposing to amend its offset regulations currently codified in 31 CFR part 285 subpart A. These regulations govern how Fiscal Service administers the offset of federal and state payments to collect federal and state debt through the Treasury Offset Program. Through the amendment, Fiscal Service will re-write and reorganize the current regulations.
  The main purpose of the amendment will be to improve the clarity of the regulations. A second purpose will be to restore flexibility where previously-issued regulations may have unintentionally narrowed statutory authority.

**Internal Revenue Service**

The Internal Revenue Service (IRS), working with the Office of Tax Policy, promulgates regulations that interpret and implement the Internal Revenue Code (Code), and other internal revenue laws of the United States. The purpose of these regulations is to carry out the tax policy determined by Congress in a fair, impartial, and reasonable manner, taking into account the intent of Congress, the realities of relevant transactions, the need for the Government to administer the rules and monitor compliance, and the overall integrity of the Federal tax system. The goal is to make the regulations practical and as clear and simple as possible, which reduces the burdens on taxpayers and the IRS.

During fiscal year 2022, the IRS and Treasury’s Office of Tax Policy’s priority is to continue providing guidance regarding implementation of key provisions of the American Rescue Plan Act of 2021, Public Law 117–2, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, Public Law 115–97, known as the Tax Cuts and Jobs Act, as well as the Taxpayer First Act, Public Law 116–25, Division O of the Further Consolidated Appropriations Act, 2020, and Public Law 116–94, known as the Setting Every Community Up for Retirement Enhancement Act of 2019 (SECURE Act).

Every year, Treasury and the IRS identify guidance projects that are priorities for allocation of the resources during the year in the Priority Guidance Plan (PGP) (available on irs.gov and regulations.gov). The plan represents projects that Treasury and the IRS intend to actively work on during the plan year. See, for example, the 2021–2022 Priority Guidance Plan (September 9, 2021). To help facilitate and encourage suggestions, Treasury and the IRS have developed an annual process for soliciting public input for guidance projects. The annual solicitation is done through the issuance of a notice inviting recommendations from the public for items to be included on the PGP for the upcoming plan year. See, for example, Notice 2021–28 (April 14, 2021). We also invite the public to continue throughout the year to provide us with their comments and suggestions for guidance projects.

**BILMING CODE 4810-25-P**

**DEPARTMENT OF VETERANS AFFAIRS (VA)**

**Statement of Regulatory Priorities**

The Department of Veterans Affairs (VA) administers services and benefit programs that recognize the important public obligations to those who served...
this Nation. VA’s regulatory responsibility is almost solely confined to carrying out mandates of the laws enacted by Congress relating to programs for veterans and their families. VA’s major regulatory objective is to implement these laws with fairness, justice, and efficiency.

Most of the regulations issued by VA involve at least one of three VA components: The Veterans Benefits Administration, the Veterans Health Administration, and the National Cemetery Administration. The primary mission of the Veterans Benefits Administration is to provide high-quality and timely nonmedical benefits to eligible veterans and their dependents. The primary mission of the Veterans Health Administration is to provide high-quality health care on a timely basis to eligible veterans through its system of medical centers, nursing homes, domiciliaries, and outpatient medical and dental facilities. The primary mission of the National Cemetery Administration is to bury eligible veterans, members of the Reserve components, and their dependents in VA National Cemeteries and to maintain those cemeteries as national shrines in perpetuity as a final tribute of a grateful Nation to commemorate their service and sacrifice to our Nation.

VA’s regulatory priority plan consists of three high priority regulations:

1. RIN 2900–AQ30 Proposed Rule—Modifying Copayments for Veterans at High Risk for Suicide

The Department of Veterans Affairs (VA) proposes to amend its medical regulations that govern copayments for outpatient medical care and medications for at-risk veterans.

2. RIN 2900–AR01 Proposed Rule—VA Pilot Program on Graduate Medical Education and Residency

The Department of Veterans Affairs proposes to revise its medical regulations to establish a new pilot program on graduate medical education and residency, as required by section 403 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Network Act of 2018.

3. RIN 2900–AR16 Interim Final Rule—Staff Sergeant Parker Gordon Fox Suicide Prevention Grant Program

The Department of Veterans Affairs (VA) is issuing this interim final rule to implement legislation authorizing VA to initiate a three-year community-based grant program to award grants to eligible entities to provide or coordinate the provision of suicide prevention services to eligible individuals and their families. This rulemaking specifies grant eligibility criteria, application requirements, scoring criteria, constraints on the allocation and use of the funds, and other requirements necessary to implement this grant program.

VA

Proposed Rule Stage

141. Modifying Copayments for Veterans at High Risk for Suicide

Priority: Other Significant.
Legal Authority: 38 U.S.C. 1710(g); 38 U.S.C. 1722A
CFR Citation: 38 CFR 17.108; 38 CFR 17.110.
Legal Deadline: None.

Abstract: The Department of Veterans Affairs (VA) proposes to amend its medical regulations that govern copayments for outpatient medical care and medications for at-risk veterans.

Statement of Need: This rulemaking is needed because a change in the current regulation is called for by the policy outlined in Executive Order 13822, which provides that our Government must improve mental healthcare and access to suicide prevention resources available to veterans. Healthcare research has provided extensive evidence that copayments can be barriers to healthcare for vulnerable patients, which places the proposed change in line with the goals of the Executive Order.

Summary of Legal Basis: Executive Order 13822.

Alternatives: The express intent of the rulemaking is to reduce barriers to mental health care for Veterans at high risk for suicide. To defer implementation of the regulation would be to undermine its purpose. However, alternative regulatory approaches were considered. It was considered whether VA national or local policy changes could effectively meet the intent of the proposed regulation. It was found that policy change is not a viable alternative due to regulatory constraints that prevent changes to copayment requirements. The timing of rulemaking was considered. There were no potential cost savings or other net benefits identified that would lead to a more beneficial option.

A phase-in period for the regulation was considered. There were no burdens, likely failures, or negative comments identified that a phase-in period would help mitigate. There were no potential cost savings or other net benefits identified that would make phasing in the regulation a more beneficial option.

Anticipated Cost and Benefits: Outpatient medical care and medication copayments will be reduced for Veterans determined to be at high risk for suicide. VA strongly believes, based on extensive empirical evidence, that the provisions of this rulemaking will decrease the likelihood of fatal or medically serious overdoses from VA prescribed medications among Veterans who are at a high risk of suicide. VA also strongly believes, based on the evidence, that the provisions of this rulemaking will significantly increase the engagement of Veterans who are at a high risk of suicide in outpatient health care, which is known to decrease the risk of suicide and other adverse outcomes.

VA has determined that there are transfers associated with this rulemaking and a loss of revenue to VA from the reduction of specific veteran copayments. The transfers are estimated to be $9.43M in FY2022 and $54.35M over a 5-year period. The loss of revenue to VA is estimated to be $0.21M in FY2022 and $1.11M over a five-year period. The total budgetary impact of this rulemaking is estimated to be $9.64M in FY2022 and $55.47M over a five-year period.

Risks: None.
Timetables:

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Regulatory Flexibility Analysis

Required: No.
Small Entities Affected: No.
Government Levels Affected: None.
Agency Contact: Julie Wildman, Informatics Educator, Department of Veterans Affairs, 795 Willow Road, Building 321, Room A124, Menlo Park, CA 94304. Phone: 650 493–5000, Email: julie.wildman@va.gov.
RIN: 2900–AQ30

VA

142. VA Pilot Program on Graduate Medical Education and Residency

Priority: Other Significant.
Legal Authority: Pub. L. 115–182, sec. 403
CFR Citation: 38 CFR 17.243 to 17.248.
Legal Deadline: None.

Abstract: The Department of Veterans Affairs proposes to revise its medical regulations to establish a new pilot program on graduate medical education and residency, as required by section

Statement of Need: This rulemaking is needed to implement section 403 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Network Act of 2018 (hereafter referred to as the MISSION Act). Section 403 of the MISSION Act requires the Department of Veterans Affairs (VA) to create a pilot program to establish additional medical residency positions authorized under section 301(b)(2) of Public Law 113–146 (note to section 7302 of title 38 United States Code (U.S.C.)) at certain covered facilities, to include non-VA facilities. Prior to section 403 of the MISSION Act, VA’s authority in 38 U.S.C. 7302 permitted VA to establish medical residency programs in VA facilities and ensure that such programs have a sufficient number of residents, where VA’s graduate medical education (GME) programming was limited to funding resident salaries and benefits only if such residents were in VA facilities, caring for Veterans, and supervised by VA staff, with some additional support to the affiliated educational institutions for educational costs. 

Summary of Legal Basis: Section 403 of the MISSION Act expanded on this authority by creating a pilot to allow VA to fund residents regardless of whether they are in VA facilities, and to pay for certain costs of new residency programs that might also not be in VA facilities. 

Alternatives: VA analyzed whether this pilot program could be implemented without regulations, because the administration of resident stipends and benefits, as well as the reimbursement of certain costs of new residency programs, would be controlled by contracts or agreements outside of regulations. However, regulations were thought necessary to: Better characterize selection criteria for the covered facilities in which residents will be placed, and to establish priority placement at certain covered facilities as required by section 403; establish criteria for defining new residency programs; qualify the resident activities that would be reimbursable; and qualify the reimbursable costs for new residency programs if VA places a resident in a new residency program. Regulations were also thought necessary to clarify that this pilot program, unlike many other VA pilot programs, is not a grant cooperative agreement program through which entities may apply to be considered for resident funding or reimbursement of new residency program costs. 

Anticipated Cost and Benefits: Increasing the number of residents and residency programs in underserved regions may improve the number of physicians practicing there after residency training and also will increase access to healthcare for veterans and possibly non-Veterans residing in those regions. 

VA estimates that costs of this program will be $4,160,259 in FY22 and $13,691,052 over a 5-year period. Transfers will be zero in FY22 and $25,687,106 over a 5-year period. Combined, this results in a budget impact of $4,160,259 in FY 22 and $39,378,158 over a 5-year window. 

Risks: None. 

VA Final Rule Stage 

143. Staff Sergeant Parker Gordon Fox Suicide Prevention Grant Program 

Priority: Other Significant. 


Abstract: The Department of Veterans Affairs (VA) is issuing this interim final rule to implement legislation authorizing VA to initiate a three-year community-based grant cooperative agreement program to provide or coordinate the provision of suicide prevention services to eligible individuals and their families. This rulemaking specifies grant eligibility criteria, application requirements, scoring criteria, constraints on the allocation and use of the funds, and other requirements necessary to implement this grant program. 

Statement of Need: The Department of Veterans Affairs (VA) is issuing regulations for the implementation of section 201 of Public Law 116–171, the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019 (the Act). Title 38 of United States Code (U.S.C.) section 501(d) requires VA to publish regulations for matters related to grants, notwithstanding section 553(a)(2) of the Administration Procedure Act. 

Summary of Legal Basis: This grant program is authorized by section 201 of Public Law 116–171. VA must publish regulations for matters related to grants as required by 38 U.S.C. 501(d). 

Alternatives: VHA initially was planning to implement the pilot program without any collaboration or planning with our internal or external partners. As an alternative, VHA intends to collaborate with other grant programs to examine certain costs which may be shared such as FTE, IT systems, and utilizing internal VA offices and infrastructure for certain aspect of grants management. This will maximize the effectiveness of the program and minimize any inefficiencies which would have otherwise arisen. VA determined the best course of action was to work with internal and external partners to develop the best grant program possible for suicide prevention among our Veteran population. 

Anticipated Cost and Benefits: VA has estimated that there are both transfers and costs associated with the provisions of this rulemaking. The transfers are estimated to be $51.7M in FY2023 and $156 7M through FY2025. The costs are estimated to be $1.6M in FY2021 and $16.8M over five years (FY2021–FY2025). 

Risks: None. 

Regulatory Flexibility Analysis 

Required: No. 

Small Entities Affected: No. 

Government Levels Affected: None. 


Agency Contact: Marjorie A. Bowman, Chief, Office of Academic Affiliations (10X1), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, Phone: 202 461–9490, Email: marjorie.bowman@va.gov. 

RIN: 2900–AR01
to protect human health and the environment and to address the climate crisis.

EPA has initiated cross-Agency efforts to address our most complex environmental challenges including PFAS pollution. Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals, including PFOA and PFOS, that have been manufactured and used in a variety of industries around the globe, including in the United States, since the 1940s. Both chemicals persist in the environment and in the human body. The EPA Administrator established a Council on PFAS, comprised of a group of senior agency leaders who are charged with accelerating the Agency’s progress on PFAS. EPA is committed to using all the Agency’s authorities to address PFAS pollution including Safe Drinking Water Act, Clean Water Act, and the Comprehensive Environmental Response, Compensation, and Liability Act. EPA also is expanding our existing data collection efforts to better understand the environmental and human health impacts of PFAS.

Similarly, EPA has developed a cross-Agency strategy to coordinate the Agency’s efforts to reduce lead exposure and protect children and families from the harmful effects of lead. EPA will use its regulatory authorities, along with grant- and incentive-based programs, technical and compliance assistance, and research and educational initiatives, to address the following priorities set forth in EPA’s upcoming Strategic Plan:

- Tackle the Climate Crisis
- Advance Environmental Justice and Civil Rights
- Ensure Clean and Healthy Air for All Communities
- Ensure Clean and Healthy Water for All Communities
- Safeguard and Revitalize Communities
- Ensure Safety of Chemicals for People and the Environment

All this work will be undertaken with a strong commitment to scientific integrity, the rule of law and transparency, the health of children and other vulnerable populations, and with special focus on supporting and achieving environmental justice at federal, tribal, state, and local levels. - 

**Highlights of EPA’s Regulatory Plan**

This Regulatory Plan highlights our most important upcoming regulatory actions. As always, our Semiannual Regulatory Agenda contains information on a broader spectrum of EPA’s upcoming regulatory actions.

**Tackle the Climate Crisis**

EPA must take bold and decisive steps to respond to the severe and urgent threat of climate change, including taking appropriate regulatory action under existing statutory authorities to reduce emissions from our nation’s largest sources of greenhouse gases (GHGs). The impacts of climate change are affecting people in every region of the country, threatening lives and livelihoods and damaging infrastructure, ecosystems, and social systems. Overburdened and underserved communities and individuals are particularly vulnerable to these impacts, including low-income communities and communities of color, children, the elderly, tribes, and indigenous people. Exercising its authority under the Clean Air Act (CAA), EPA will address major sources of GHGs that are driving these impacts by taking regulatory action to minimize emissions of methane from new and existing sources in the oil and natural gas sector; reduce GHGs from new and existing fossil fuel-fired power plants; limit GHGs from new light-duty vehicles and heavy-duty trucks; and set requirements for the use of renewable fuel. EPA will also carry out the mandates of the recently enacted American Innovation and Manufacturing (AIM) Act to implement, and where appropriate accelerate, a national phasedown in the production and consumption of hydrofluorocarbons (HFCs), which are highly potent GHGs.

- **Emission Guidelines for Oil and Natural Gas Sector.** The oil and natural gas industry are the largest industrial source of U.S. emissions of methane, a GHG more than 25 times as potent as carbon dioxide at trapping heat in the atmosphere. Executive Order 13990, “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,” states that the Administrator of EPA should consider proposing new regulations to establish emission guidelines for methane emissions from existing operations in the oil and gas sector, including the exploration and production, transmission, processing, and storage segments. The purpose of this action is to propose new emission guidelines for existing sources in the oil and gas sector by October 2021.
- **New Source Performance Standards for Crude Oil and Natural Gas Facilities:** Review of Policy and Technical Rules. Executive Order 13990 further directs EPA to review the new source performance standards (NSPS) issued in 2020 for the oil and gas sector about methane and volatile organic compound.
(VOC) emissions and, as appropriate and consistent with applicable law, consider publishing for notice and comment a proposed rule suspending, revising, or rescinding the NSPS. The Executive Order also directs EPA to consider proposing new regulations to establish comprehensive NSPS for methane and VOC emissions from the exploration and production, transmission, processing, and storage segments. The purpose of this action is to review the existing NSPS and propose new standards as necessary.

**Emission Guidelines for Greenhouse Gas Emissions from Fossil-Fueled Electric Generating Units.** On January 19, 2021, the D.C. Circuit Court vacated the Affordable Clean Energy Rule (40 CFR part 60, subpart UUUUa) and remanded the rule to EPA for further consideration consistent with its decision. On February 12, 2021, considering the court’s decision, the EPA published a memorandum on the status of the Affordable Clean Energy (ACE) rule and informed states not to continue the development or submittal of state plans in accordance with CAA section 111(d) guidelines for GHG emissions from power plants at this time. EPA continues to review the court’s vacatur and remand of these actions. The anticipated proposal date for this action is by July 2022, and promulgation by July 2023.

- **Amendments to the NSPS for GHG Emissions from New, Modified, & Reconstructed Stationary Sources: EGUs.** Under CAA section 111(b), EPA sets New Source Performance Standards (NSPS) for GHG emissions from new, modified, and reconstructed fossil fuel-fired power plants. In 2015, EPA finalized regulations to limit GHG emissions from new fossil-fuel fired utility boilers and from natural gas-fired stationary combustion turbines. In 2018, EPA proposed to revise the NSPS for coal fired EGUs. To date, that proposed action has not been finalized. The 2018 proposed rule would have revised the 2015 NSPS in conjunction with the Clean Power Plan (80 FR 64510). Litigation remains in abeyance for the 2015 final NSPS. The purpose of this action is to review the NSPS and, if appropriate, amend the standards for new fossil fuel-fired EGUs. Anticipated timing of the proposed rule is by June 2022 and promulgation by June 2023.

- **Restrictions on Certain Uses of Hydrofluorocarbons under Subsection (i) of the American Innovation and Manufacturing Act.** EPA intends to propose a rule in part, responsive to petitions granted under subsection (i) of the AIM Act. Subsection (i) of the AIM Act provides that a person may petition EPA to promulgate a rule for the restriction on use of a regulated substance in a sector or subsector. EPA will consider a rule restricting, fully, partially, or on a graduated schedule, the use of HFCs in sectors or subsectors including the refrigeration, air conditioning, aerosol, and foam sectors informed by petitions received from environmental groups, trade associations, and individual companies. Additionally, EPA will consider establishing recordkeeping and reporting requirements and addressing other related elements of the AIM Act.

- **Phasedown of Hydrofluorocarbons: Updates to the Allowance Allocation and Trading Program under the American Innovation and Manufacturing Act for 2024 and Later Years.** As noted above, the AIM Act directs EPA to sharply reduce production and consumption of HFCs, which are harmful and potent greenhouse gases, by using an allowance allocation and trading program. This phasedown will decrease the production and import of HFCs in the United States by 85% over the next 15 years. The first regulation under the AIM Act established the allowance allocation and trading program for 2022 and 2023. To continue phasing down the production and consumption of listed HFCs on the schedule listed in the AIM Act, this rulemaking will provide the framework for how the Agency will issue allowances in 2024 and beyond.

- **Revised 2023 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions Standards.** Executive Order 13990 directed EPA to review the Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks (April 30, 2020). In August 2021, EPA proposed to revise existing national GHG emissions standards for passenger cars and light trucks for Model Years 2023–2026. The proposed standards would achieve significant GHG emissions reductions along with reductions in other criteria pollutants. The proposal would result in substantial public health and welfare benefits, while providing consumers with savings from lower fuel costs.

- **Volume Requirements for 2023 and Beyond under the Renewable Fuel Standard Program.** CAA statutory provisions governing the Renewable Fuel Standard (RFS) program provide target volumes of renewable fuel for the RFS program only through 2022. For years 2023 and thereafter, the statute requires the use of these volumes based on an analysis of specified factors. If EPA does not set those volumes, there will be no applicable requirement to blend renewable fuel into gasoline and diesel. This rulemaking will establish volume requirements for 2023 and some years beyond. The proposal will provide the public with an opportunity to provide feedback on various alternative volume requirements.

- **Renewable Fuel Standard (RFS) Program: RFS Annual Rules.** CAA section 211 requires EPA to set renewable fuel percentage standards every year. This action establishes the annual percentage standards for cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel that apply to gasoline and diesel transportation fuel.

**Ensure Clean and Healthy Air for All Communities**

All people regardless of race, ethnicity, national origin, or income deserve to breathe clean air. EPA has the responsibility to protect the health of vulnerable and sensitive populations, such as children, the elderly, and persons overburdened by pollution or adversely affected by persistent poverty or inequality. Since enactment of the CAA, EPA has made significant progress in reducing harmful air pollution even as the U.S. population and economy have grown. Between 1970 and 2020, the combined emissions of six key pollutants dropped by 78%, while the U.S. economy remained strong growing 272% over that time period. As required by the CAA, EPA will continue to build on this progress and work to ensure clean air for all Americans, including those in underserved and overburdened communities. Among other things, EPA will take regulatory action to review and implement health-based air quality standards for criteria pollutants such as particulate matter (PM); limit emissions of harmful air pollution from both stationary and mobile sources; address sources of hazardous air pollution (HAP), such as ethylene oxide, that disproportionately affect communities with environmental justice concerns; and protect downwind communities from sources of air pollution that cross state lines. Along with the full set of CAA actions listed in the regulatory agenda, the following high priority actions will allow EPA to continue its progress in reducing harmful air pollution.

- **Review of the National Ambient Air Quality Standards for Particulate Matter.** Under the CAA Amendments of 1977, EPA is required to review and if appropriate revise the air quality criteria for major primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS)
every 5 years. In December 2020, EPA published its final decision in the review of the PM NAAQS, retaining the existing standard established in 2013. The review included the preparation of an Integrated Review Plan, an Integrated Science Assessment (ISA), and a Policy Assessment with opportunities for review by EPA’s Clean Air Scientific Advisory Committee (CASAC) and the public. These documents informed the Administrator’s decision in the PM NAAQS review. On June 10, 2021, EPA notified the public that it will reconsider the 2020 decision to retain the PM NAAQS. As part of this reconsideration, EPA intends to develop a supplement to the ISA and a revised policy assessment to consider the most up-to-date science on public health and welfare impacts of PM and to engage with the CASAC and a newly constituted expert PM panel. Additionally, on July 7, 2020, EPA notified the public that it was initiating an update of the ISA for lead as part of the periodic review of the lead NAAQS.

- **NESHAP: Coal- and Oil-Fired Electric Utility Steam Generating Units—Revocation of the 2020 Reconsideration, and Affirmation of the Appropriate and Necessary Supplemental Finding.** Executive Order 13990 directs EPA to take certain actions by August 2021, including considering publishing, as appropriate and consistent with applicable law, a proposed rule suspending, revising, or rescinding the “National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units—Reconsideration of Supplemental Finding and Residual Risk and Technology Review,” 85 FR 31286 (May 22, 2020). The May 2020 final action is the latest amendment to the February 16, 2012, National Emission Standards for Hazardous Air Pollutants for Coal- and Oil-Fired Electric Utility Steam Generating Units (77 FR 9304). That 2012 rule (40 CFR part 63, subpart UUUUUU), commonly referred to as the Mercury and Air Toxics Standards (MATS), includes standards to control HAP emissions from new and existing coal- and oil-fired steam EGUs located at both major and area sources of HAP emissions. In the May 22, 2020 action, EPA found that it is not appropriate and necessary to regulate coal- and oil-fired EGUs under CAA section 112. As directed by E.O. 13990, EPA will review the May 22, 2020, finding and, under this action, will take appropriate action resulting from its review of the May 2020 finding that it is not appropriate and necessary to regulate coal- and oil-fired EGUs under Clean Air Act section 112. Results of EPA’s review of the May 2020 RTR will be presented in a separate action.

- ** Interstate Transport Rule for 2015 Ozone NAAQS.** This action would apply in certain states for which EPA has either disapproved a “good neighbor” state implementation plan (SIP) submission under CAA section 110(a)(2)(D)(i)(I) or has made a finding of failure to submit such a SIP submission for the 2015 ozone NAAQS. This action would determine whether and to what extent upwind sources of ozone-precursor emissions need to reduce these emissions to prevent interference with downwind states’ maintenance or attainment of the 2015 8-hour ozone NAAQS. For upwind states that EPA determines to be linked to a downwind nonattainment or maintenance receptor, EPA would conduct further analysis to determine what (if any) additional emissions controls are required in such states and develop an enforceable program for implementation of such controls.

- **Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards.** Heavy-duty engines have been subject to emission standards for criteria pollutants, including PM, hydrocarbon (HC), carbon monoxide (CO), and oxides of nitrogen (NOx), for nearly half a century. Current data suggest that existing standards should be revised to ensure full, in-use emission control. NOx emissions are major precursors of ozone and significant contributors to secondary PM2.5 formation. Ozone and ambient PM2.5 concentrations continue to be a nationwide health and air quality issue. Reducing NOx emissions from on-highway, heavy-duty trucks and buses is an important component of improving air quality nationwide and reducing public health and welfare effects associated with these pollutants, especially for vulnerable populations and in highly impacted regions. Through this action, EPA will evaluate data on current NOx emissions from heavy-duty vehicles and engines and propose options to improve control of criteria pollutant emissions through revised emissions standards. Additionally, this action will propose updates to the existing greenhouse gas emissions standards for heavy-duty vehicles.

- **National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations.** In response to EPA’s National Air Toxics Assessment (NATA), which identified several areas across the country as having the potential for elevated cancer risk due to emissions of ethylene oxide to the outdoor air, EPA has initiated a review of its existing air rules for source categories that emit this chemical. This includes reviewing the current National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations, which were finalized in December 1994 (59 FR 62585). The standards require existing and new major sources to control emissions to the level achievable by the maximum achievable control technology (MACT) and require existing and new area sources to control emissions using generally available control technology (GACT). In this action, EPA will conduct a statutorily required technology review for the NESHAP and will also consider the cancer risks of ethylene oxide emissions from this source category. To aid in this effort, EPA issued an advance notice of proposed rulemaking (ANPRM) on December 12, 2019 (84 FR 67889) that solicited comment from stakeholders, developed important emissions-related data through data collection activities, and undertook a Small Business Advocacy Review (SBAR) panel, which is needed when there is the potential for significant economic impacts to small businesses from any regulatory actions being considered.

- **Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act.** This rulemaking will address the review of the final rule, “Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act” (Major MACT to Area, or MM2A final rule). See 85 FR 73854, November 19, 2020. Pursuant to Executive Order 13990, EPA has decided to review the MM2A final rule and, as appropriate and consistent with the CAA section 112, to publish for comment a notice of proposed rulemaking either suspending, revising, or rescinding the MM2A final rule. The MM2A final rule became effective on January 19, 2021 and provides that a major source can be reclassified to area source status at any time upon reducing its potential to emit (PTE) HAP to below the major source thresholds (MST) of 10 tons per year (tpy) of any single HAP and 25 tpy of any combination of HAP. Major sources that reclassify to area source status will no longer be subject to CAA section 112 major source requirements and, instead, will be subject to any applicable area source requirements. The MM2A final rule also included an interim ministerial revision
that removed the word “federally” from the phrase “federally enforceable” in the PTE definition in 40 CFR 63.2.

**Ensure Clean and Healthy Water for All Communities**

The Nation’s water resources are the lifeblood of our communities, supporting our health, economy, and way of life. Clean and safe water is a vital resource that is essential to the protection of human health. The EPA is committed to ensuring clean and safe water for all, including low-income communities and communities of color, children, the elderly, tribes, and indigenous people. Since the enactment of the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA), EPA and its state and tribal partners have made significant progress toward improving the quality of our waters and ensuring a safe drinking water supply. Along with the full set of water actions listed in the regulatory agenda, the regulatory initiatives listed below will help ensure that this important progress continues.

- **Revised Definition of “Waters of the United States”—Rule 1:** In April 2020, the EPA, and the Department of the Army (“the agencies”) published the Navigable Waters Protection Rule (NWPR) that revised the previously-codified definition of “waters of the United States” (85 FR 22250, April 21, 2020). The agencies are now initiating this new rulemaking process that restores the regulations in place prior to the 2015 “Clean Water Rule: Definition of Waters of the United States” (80 FR 37054, June 29, 2015), updated to be consistent with relevant Supreme Court decisions. The agencies intend to consider further revisions in a second rule in light of additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

- **Revised Definition of “Waters of the United States”—Rule 2:** The EPA and the Department of the Army (“the agencies”) intend to pursue a second rule defining “Waters of the United States” to consider further revisions to the agencies’ first rule (RIN 2040–AG13) which proposes to restore the regulations in place prior to the 2015 “Clean Water Rule: Definition of Waters of the United States” (80 FR 37054, June 29, 2015), updated to be consistent with relevant Supreme Court Decisions. This second rule proposes to include revisions reflecting on additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

- **Clean Water Act Section 401: Water Quality Certification.** In accordance with Executive Order 13990, EPA has completed its review of the 2020 Clean Water Act Section 401 Certification Rule (85 FR 42210, July 13, 2020) and has determined that it erodes state and tribal authority as it relates to protecting water quality. Through the new rulemaking, EPA intends to restore the balance of state, tribal, and federal authorities while retaining elements that support efficient and effective implementation of section 401. Congress provided authority to states and tribes under CWA section 401 to protect the quality of their waters from adverse impacts resulting from federally licensed or permitted projects. Under section 401, a federal agency may not issue a license or permit to conduct any activity that may result in any discharge into navigable waters unless the affected state or tribe certifies that the discharge is in compliance with the CWA and state law or waivers certification. EPA intends to strengthen the authority of states and tribes to protect their vital water resources.

- **Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category.** On July 26, 2021, EPA announced its decision to conduct a rulemaking to potentially strengthen the Steam Electric Effluent Limitations Guidelines (ELGs) (40 CFR 423). This rulemaking process could result in more stringent ELGs for waste streams addressed in the 2020 final rule, as well as waste streams not covered in the 2020 rule. The former could address petitioners’ claims in current litigation pending in the Fourth Circuit Court of Appeals. Appalachian Voices v. EPA, No. 20–2187 (4th Cir.). EPA revised the Steam Electric ELGs in 2015 and 2020.

- **Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking.** On March 3, 2021, EPA published the Fourth Regulatory Determinations (86 FR 12272), including a determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) in drinking water. With this decision, EPA intends to develop a proposed national primary drinking water regulation for PFOA and PFOS, and, as appropriate, take final action. Additionally, EPA will continue to consider other PFAS as part of this action.

- **National Primary Drinking Water Regulations for Lead and Copper: Regulatory Revisions.** EPA promulgated the final Lead and Copper Rule Revision (LCRR) on January 15, 2021 (86 FR 4198). Consistent with the directives of Executive Order 13990, EPA is currently considering revising this rulemaking. EPA will complete its review of the rule by December 2021 in accordance with those directives and informed by a robust stakeholder engagement process, including hearing from low-income people and communities of color who are disproportionately affected by lead contamination. EPA understands that the benefits of clean water are not shared equally by all communities, and this review of the LCRR will be consistent with the policy aims set forth in Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities through the Federal Government.”

- **Cybersecurity in Public Water Systems.** EPA is evaluating regulatory approaches to ensure improved cybersecurity at public water systems. EPA plans to offer separate guidance, training, and technical assistance to states and public water systems on cybersecurity. This action is expected to provide regulatory clarity and certainty and promote the adoption of cybersecurity measures by public water systems.

- **Federal Baseline Water Quality Standards for Indian Reservations.** EPA is developing a proposed rule to establish tribal baseline water quality standards (WQS) for waters on Indian reservations that do not have WQS under the CWA. The development of this rule will help advance President Biden’s commitment to strengthening the nation-to-nation relationships with Indian Country. Currently, less than 20 percent of reservations have EPA-approved tribal WQS. Promulgating baseline WQS would address this longstanding gap and provide more scientific rigor and regulatory certainty to National Pollutant Discharge Elimination System (NPDES) permits for discharges to these waters. Consistent with EPA’s regulations, the baseline WQS would include designated uses, water quality criteria to protect those uses, and antidegradation policies to protect high quality waters. EPA has consulted with tribes and will continue to do so.
Safeguard and Revitalize Communities

EPA works to improve the health and livelihood of all Americans by cleaning up and returning land to productive use, preventing contamination, and responding to emergencies. EPA collaborates with other federal agencies, industry, states, tribes, and local communities to enhance the livability and economic vitality of neighborhoods. Challenging and complex environmental problems persist at many contaminated properties, including contaminated soil, sediment, surface water, and groundwater that can cause human health concerns. EPA’s regulatory program works to incorporate new technologies and approaches to cleaning up land to provide for an environmentally sustainable future more efficiently and effectively, as well as to create resilience and to integrate environmental justice and equitable development when returning sites to productive use. Along with the other land and emergency management actions in the regulatory agenda, EPA will take the following priority actions to address the contamination of soil, sediment, surface water, and groundwater.

- Designation of Perfluorooctanoic and Perfluorooctanesulfonic Acids as Hazardous Substances. EPA issued a PFAS Action Plan on February 14, 2019, responding to extensive public interest and input. The plan announced that EPA will begin the steps necessary to propose designating PFOA and PFOS as hazardous substances through one of the available statutory mechanisms in section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). CERCLA, commonly known as Superfund, provides EPA with enforcement authority and establishes liability for releases or threatened releases of hazardous substances. Designating PFOA and PFOS as CERCLA hazardous substances will require reporting of releases of PFOA and PFOS that meet or exceed the reportable quantity assigned to these substances. This will enable federal, state, tribal and local authorities to collect information regarding the location and extent of release. Moreover, designating PFOS and PFOA as hazardous substances under CERCLA would expand EPA’s authority to investigate or respond to a release, and, thereby, reduce harm or risk to human health, welfare, and the environment.

- Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residues from Electric Utilities. EPA is planning to amend the existing regulations in 40 CFR part 257 on the disposal of Coal Combustion Residuals (CCR) under subtitle D of the Resource Conservation and Recovery Act, initially issued on April 17, 2015 (80 FR 21302). By implementing the April 2015 final rule, EPA is working to ensure that CCR disposal units that do not meet rule requirements, including unlined surface impoundments, cease receipt of waste and close in a way that protects public health and the environment. In addition, the Water Infrastructure Improvements for the Nation Act of 2016 established new statutory provisions applicable to CCR disposal units and authorized EPA, if provided specific appropriations, to develop a federal permit program in nonparticipating states for CCR units. EPA plans to finalize regulatory amendments to provide a federal CCR permitting program. Finally, EPA plans to propose a rule to regulate inactive CCR surface impoundments at inactive utilities, or “legacy units.”

Accidental Release Prevention Requirements Risk Management Program (RMP) under the Clean Air Act; Retrospection. In accordance with Executive Order 13990, EPA is revising the RMP regulations, which implement the requirements of CAA section 112(r)(7). RMP requires facilities that use extremely hazardous substances to develop a Risk Management Plan. In 2019, EPA finalized a reconsideration of the RMP regulations that eliminated many of the major incident prevention initiatives that had been established in 2017 amendments to the rule. To support the current revisions, EPA hosted listening sessions to provide interested stakeholders the opportunity to present information or comment on issues pertaining to these revisions.

Ensure Safety of Chemicals for People and the Environment

EPA is responsible for ensuring the safety of chemicals and pesticides for all people at all stages. Chemicals and pesticides released into the environment as a result their manufacture, processing, distribution, use, or disposal can threaten human health and the environment. EPA gathers and assesses information about the risks associated with chemicals and pesticides and acts to minimize risks and prevent unreasonable risks to individuals, families, and the environment. EPA acts under several different statutory authorities, including the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), the Toxic Substances Control Act (TSCA), the Emergency Planning and Community Right-to-Know Act (EPCRA), and the Pollution Prevention Act (PPA). Using best available science, the Agency will continue to satisfy its overall directives under these authorities and highlights the following rulemakings intended for release in FY2022:

- Chemical Specific Risk Management Rulemakings under TSCA section 6(a). As amended in 2016, TSCA requires EPA to evaluate the safety of existing chemicals via a three-stage process: Prioritization, risk evaluation, and risk management. EPA first prioritizes chemicals as either high- or low-priority for risk evaluation. EPA evaluates high-priority chemicals for unreasonable risk. If, at the end of the risk evaluation process, EPA determines that a chemical presents an unreasonable risk to health or the environment, the Agency must immediately move the chemical to risk management action under TSCA. EPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing, distribution, use or disposal of the chemical to eliminate the unreasonable risk. TSCA gives EPA a range of risk management options, including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, or a ban of the chemical or of certain uses.

As announced on June 30, 2021, EPA reviewed the TSCA risk evaluations issued for the first 10 chemicals and as a result intends to implement policy changes to ensure the Agency is protecting human health and the environment under the requirements of TSCA. Upon review of the risk evaluations issued for Cyclic Aliphatic Bromide Cluster (HBCD) (RIN 2070–AK71), C.I. Pigment Violet 29 (PV29) (RIN 2070–AK87), and asbestos (part 1: Chrysotile asbestos) (RIN 2070–AK86), EPA currently believes these risk evaluations are likely sufficient to inform the risk management approaches being considered and that these approaches will be protective; therefore, the Agency does not think it needs to conduct any additional technical analysis that would amend the risk evaluation. However, EPA does intend to reissue individual chemical risk determinations that amend the approach to personal protective equipment (PPE) and include a whole chemical risk determination for HBCD (RIN 2070–AK71) and PV29 (RIN 2070–AK87) and, during part 2 of the risk evaluation for asbestos. The Agency is also working expeditiously on risk management and believes the proposed HBCD (RIN 2070–AK71) and asbestos (part 1: Chrysotile asbestos) (RIN 2070–AK86)
will likely be the first of the 10 to be ready for release in FY2022.

- **Modification to the Minimum Risk Pesticide Listing Program.** Under FIFRA section 25(b), EPA has determined that certain “minimum risk pesticides” pose little to no risk to human health or the environment and has exempted them from registration and other requirements under FIFRA. In 1996, EPA created a regulatory list of minimum risk active and inert ingredients in 40 CFR 152.25. Such exemption reduces the cost and regulatory burdens on businesses and the public for those pesticides deemed to pose little or no risk and allows EPA to focus our resources on pesticides that pose greater risk to humans and the environment. EPA is considering streamlining the petition process and revising how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions, state implementation of the minimum risk program, and the need for any future exemptions or modifications to current exemptions. On April 8, 2021 (86 FR 18232), EPA issued an advance notice of proposed rulemaking to solicit public input that it is considering in developing a proposed rule that the Agency intends to issue in FY2022.

**Rules Expected To Affect Small Entities**

By better coordinating small business activities, EPA aims to improve its technical assistance and outreach efforts, minimize burdens to small businesses in its regulations, and simplify small businesses’ participation in its voluntary programs. Actions that may affect small entities can be tracked on EPA’s Regulatory Flexibility website (https://www.epa.gov/reg-flex) at any time.

**EPA—OFFICE OF AIR AND RADIATION (OAR)**

**Proposed Rule Stage**

144. National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations

**Priority:** Other Significant.

**Legal Authority:** 42 U.S.C. 7412 Clean Air Act; 42 U.S.C. 7607(d)(7)(B)

**CFR Citation:** 40 CFR 63.

**Legal Deadline:** None.

**Abstract:** The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations were finalized in December 1994 (59 FR 62585). The standards require existing and new major sources to control emissions to the level achievable by the maximum achievable control technology (MACT) and require existing and new area sources to control emissions using generally available control technology (GACT). EPA completed a residual risk and technology review for the NESHAP in 2006 and, at that time, concluded that no revisions to the standards were necessary. In this action, EPA will conduct the second technology review for the NESHAP and also assess potential updates to the rule. To aid in this effort, EPA issued an advance notice of proposed rulemaking (ANPRM) that solicited comment from stakeholders and undertook a Small Business Advocacy Review (SBAR) panel, which is needed when there is the potential for significant economic impacts to small businesses from any regulatory actions being considered. EPA is also planning to undertake community outreach as part of the development of this action.

**Statement of Need:** The National Air Toxics Assessment (NATA) released in August 2018 identified ethylene oxide (EtO) emissions as a potential concern in several areas across the country. The latest NATA estimates that EtO significantly contributes to potential elevated cancer risks in some census tracts. These elevated risks are largely driven by an EPA risk value that was updated in December 2016. Further investigation on NATA inputs and results led to the EPA identifying commercial sterilization using EtO as a source category contributing to some of these risks. Over the past two years, the EPA has been gathering additional information to help evaluate opportunities to reduce EtO emissions in this source category through potential NESHAP revisions. In this rule, EPA will address EtO emissions from commercial sterilizers.

**Summary of Legal Basis:** CAA section 112, 42 U.S.C. 7412, provides the legal framework and basis for regulatory actions addressing emissions of hazardous air pollutants from stationary sources. CAA section 112(d)(6) requires EPA to review, and revise as necessary, emission standards promulgated under CAA section 112(d) at least every 8 years, considering developments in practices, processes, and control technologies.

**Alternatives:** EPA is evaluating various options for reducing EtO emissions from commercial sterilizers under the NESHAP, such as pollution control equipment, reducing fugitive emissions, or monitoring.

**Anticipated Cost and Benefits:** Based on conversations with regulated entities who have been working to reduce emissions, the potential costs of controlling some emissions sources could be substantial.

**Risks:** As part of this rulemaking, EPA has been updating information regarding EtO emissions and the specific emission points within the source category. Preliminary analyses suggest that fugitive emissions from commercial sterilizers may substantially contribute to health risks associated with exposure to EtO.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Yes.

**Small Entities Affected:** Businesses.

**Government Levels Affected:** None.

**Additional Information:**

- Sectors Affected: 311423 Dried and Dehydrated Food Manufacturing; 33911 Medical Equipment and Supplies Manufacturing; 561910 Packaging and Labeling Services; 325412 Pharmaceutical Preparation Manufacturing; 311942 Spice and Extract Manufacturing

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**EPA—OAR**

145. Control of Air Pollution From New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards

**Priority:** Economically Significant.

Major under 5 U.S.C. 801.

**Unfunded Mandates:** Undetermined.

**Legal Authority:** 42 U.S.C. 7414 et seq.

**Clean Air Act**

**CFR Citation:** 40 CFR 86.

**Legal Deadline:** None.

**Abstract:** Heavy-duty engines have been subject to emission standards for criteria pollutants, including particulate matter (PM), hydrocarbon (HC), carbon monoxide (CO), and oxides of nitrogen (NOx), for nearly half a century; however, current data suggest that the
existing standards do not ensure full, in-use emission control. In particular, in-use engine NO\textsubscript{X} emission levels from heavy-duty vehicles can be significantly higher than their certified values under certain conditions. NO\textsubscript{X} emissions are major precursors of ozone and significant contributors to secondary PM\textsubscript{2.5} formation. Ozone and ambient PM\textsubscript{2.5} concentrations continue to be a nationwide health and air quality issue. Reducing NO\textsubscript{X} emissions from on-highway, heavy-duty trucks and buses is an important component of improving air quality nationwide and reducing public health and welfare effects associated with these pollutants, especially for vulnerable populations and in highly impacted regions. This action will evaluate data on current NO\textsubscript{X} emissions from heavy-duty vehicles and engines, and options available to improve control of criteria pollutant emissions through revised NO\textsubscript{X} standards. Additionally, this action will contain targeted greenhouse gas (GHG) reductions and evaluate ways to streamline existing requirements. This rulemaking will address significant public health and environmental justice concerns caused by pollution from internal combustion engines while supporting early introduction of zero emission technologies.

**Statement of Need:** This action follows petitions for a rulemaking on this issue from over 20 organizations including state and local air agencies from across the country.

**Summary of Legal Basis:** CAA section 202(a).

**Alternatives:** EPA may request comment to address alternative options in the proposed rule.

**Anticipated Cost and Benefits:** Updating these standards will result in NO\textsubscript{X} reductions from mobile sources and could be one important way that allows areas across the U.S. to meet National Ambient Air Quality Standards for ozone and particulate matter. Updating the standards will also offer opportunities to reduce regulatory burden through smarter program design.

**Risks:** EPA will evaluate the risks of this rulemaking.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Undetermined.

**Government Levels Affected:** Undetermined.

**Federalism:** Undetermined.

**International Impacts:** This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Additional Information:**

**Sectors Affected:** 11 Agriculture, Forestry, Fishing and Hunting; 21 Natural Gas Liquid Extraction; 32 Petroleum Refineries; 325 Petrochemical Manufacturing; 325193 Ethyl Alcohol Manufacturing; 325199 All Other Basic Organic Chemical Manufacturing; 333618 Other Engine Equipment Manufacturing; 335312 Motor and Generator Manufacturing; 336111 Automobile Manufacturing; 336112 Light Truck and Utility Vehicle Manufacturing; 336120 Heavy Duty Truck Manufacturing; 336211 Motor Vehicle Body Manufacturing; 336213 Motor Home Manufacturing; 336311 Carburetor, Piston, Piston Ring, and Valve Manufacturing; 336312 Gasoline Engine and Engine Parts Manufacturing; 336999 All Other Transportation Equipment Manufacturing; 423110 Automobile and Other Motor Vehicle Merchant Wholesalers; 424690 Other Chemical and Allied Products Merchant Wholesalers; 424710 Petroleum Bulk Stations and Terminals; 486910 Pipeline Transportation of Refined Petroleum Products; 493130 Farm Product Warehousing and Storage; 811111 General Automotive Repair; 811112 Automotive Exhaust System Repair; 811198 All Other Automotive Repair and Maintenance.

**Agency Contact:** Tuana Phillips, Environmental Protection Agency, Office of Air and Radiation, 1200 Pennsylvania NW, Washington, DC 20460, Phone: 410 267–5704, Email: philips.tuana@epa.gov.

**Christy Parsons, Environmental Protection Agency, Office of Air and Radiation, USEPA National Vehicle and Fuel Emissions Laboratory, Ann Arbor, MI 48105, Phone: 734 214–4243, Email: parsons.christy@epa.gov.**

**RIN:** 2060–AU41

**EPA—OAR**

**146. Amendments to the NSPS for GHG Emissions From New, Modified, and Reconstructed Stationary Sources:** EGUS

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Unfunded Mandates:** Undetermined.

**Legal Authority:** 42 U.S.C. 7411 Clean Air Act

**CFR Citation:** 40 CFR 60 TTTT.

**Legal Deadline:** None.

**Abstract:** On October 23, 2015, the EPA finalized Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Generating Units, found at 40 CFR part 60, subpart TTTT. On December 20, 2018, the EPA proposed to revise the standards of performance in 40 CFR part 60, subpart TTTT. The EPA proposed to amend the previous determination that the best system of emission reduction (BSER) for newly constructed coal-fired steam generating units (i.e., EGUs) is partial carbon capture and storage, and replace it with a determination that BSER for this source category is the most efficient demonstrated steam cycle (e.g., supercritical steam conditions for large units and subcritical steam conditions for small units) in combination with the best operating practices. The EPA is undertaking a comprehensive review of the NSPS for greenhouse gas emissions from EGUs, including a review of all aspects of the 2018 proposed amendments and requirements in the 2015 Rule that the Agency did not propose to amend in the 2018 proposal.

**Statement of Need:** New EGUs are a significant source of GHG emissions. This action will evaluate options to reduce these emissions.

**Summary of Legal Basis:** Clean Air Act section 111(b) provides the legal framework for establishing greenhouse gas emission standards for new electric generating units.

**Alternatives:** EPA evaluated several options for reducing GHG emissions from new EGUs

**Anticipated Cost and Benefits:** Undetermined.

**Risks:** Undetermined.

**Timetable:**

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**Regulatory Flexibility Analysis**

**Required:** Undetermined.

**Government Levels Affected:** Undetermined.

**Federalism:** Undetermined.

**International Impacts:** This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Additional Information:**

**Agency Contact:** Christian Fellner, Environmental Protection Agency, Office of Air and Radiation, 109 T.W. Alexander Drive, Mail Code D243–01, Research Triangle Park, NC 27711, Phone: 919 541–4003, Fax: 919 541–4991, Email: fellner.christian@epa.gov.
EPA—OAR

147. Emission Guidelines for Greenhouse Gas Emissions From Fossil Fuel-Fired Existing Electric Generating Units


Legal Authority: 42 U.S.C. 7411 Clean Air Act

CFR Citation: 40 CFR 60 UUUU.

Legal Deadline: None.

Abstract: On January 19, 2021, the D.C. Circuit Court issued an opinion vacating the Affordable Clean Energy Rule (found at 40 CFR part 60, subpart UUUU)—the previously applicable emission guidelines for greenhouse gas (GHG) emissions from existing electric generating units (i.e. EGUs). The EPA is working on a new set of emission guidelines for states to follow in submitting state plans to establish and implement standards of performance for greenhouse gas emissions from existing fossil fuel-fired EGUs.

Statement of Need: There are no EPA regulations on the books for greenhouse gases from existing fossil-fuel fired electric generating units. Previous regulations of this nature have either been vacated or repealed prior to implementation.

Summary of Legal Basis: Clean Air Act section 111(d) provides the legal framework for establishing greenhouse gas emission standards for existing electric generating units.

Alternatives: There are no alternatives at this time.

Anticipated Cost and Benefits: EPA is still evaluating the scope and associated costs, benefits and reductions with a prospective rule.

Risks: EPA is still evaluating the scope and risks with a prospective rule.

Timetable:

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Summary of Legal Basis: CAA section 111(d).

Alternatives: EPA is considering alternative volume standards in the development of the proposal, including a response to the D.C. Circuit remand of the rule establishing the RFS volumes for 2016. We intend to continue to consider alternatives as we develop the proposed rule.

Anticipated Cost and Benefits: Anticipated costs will be developed for the proposed rule. Costs and benefits of this rulemaking account for the nature of the program and the nested structure of the volume requirements. An updated estimate of the costs, based on a number of illustrative assumptions, will be provided in the proposed rule.

Risks: Environmental and resource impacts of the RFS program are primarily addressed under another section of the CAA (Section 204). EPA released an updated report to congress on June 29, 2018. More information on this report can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=341491.

Regulatory Flexibility Analysis Required: No.

Small Entities Affected: No.


Additional Information:

Sectors Affected: 325199 All Other Basic Organic Chemical Manufacturing; 325193 Ethyl Alcohol Manufacturing; 221210 Natural Gas Distribution; 111120 Oilseed (except Soybean) Farming; 424710 Petroleum Bulk Stations and Terminals; 324110 Petroleum Refineries; 424720 Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals).

Agency Contact: Dallas Burkholder, Environmental Protection Agency, Office of Air and Radiation, NVFEL, 2565 Plymouth Road, Ann Arbor, MI 48105, Phone: 734 214–4766, Email: burkholder.dallas@epa.gov.

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Related RIN: Related to 2060–AV11

RIN: 2060–AV10

EPA—OAR


Legal Authority: 42 U.S.C. 7414 et seq.

Clean Air Act

CFR Citation: 40 CFR 80.


Abstract: Under section 211 of the Clean Air Act, the Environmental Protection Agency (EPA) is required to set renewable fuel percentage standards every year. This action establishes the annual percentage standards for cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel that apply to gasoline and diesel transportation fuel.

Statement of Need: The Clean Air Act requires EPA to promulgate regulations that specify the annual volume requirements for renewable fuels under the Renewable Fuel Standard (RFS) program. The RFS program was created under the Energy Independence and Security Act of 2007 to “move the United States toward greater energy independence and security, to increase the production of clean renewable fuels, to protect consumers, to increase the efficiency of products, buildings, and vehicles, to promote research on and deploy greenhouse gas capture and storage options, and to improve the energy performance of the Federal Government.”

Regulatory Flexibility Analysis Required: No.

Small Entities Affected: No.

Government Levels Affected: Federal, State, Tribal.
Appropriate and Necessary
Reconsideration, and Affirmation of the
Units—Revocation of the 2020
Electric Utility Steam Generating
149. NESHAP: Coal- and Oil-Fired
EPA—OAR
Standards for Hazardous Air Pollutants: Coal- and Oil-
fired Electric Utility Steam Generating
Units—Revocation of the 2020
Electric Utility Steam Generating
Units—Reconsideration, and Affirmation of the
Appropriate and Necessary
Supplemental Finding

Priority: Other Significant.
Legal Authority: 42 U.S.C. 7412 Clean
Air Acts 42 U.S.C. 7607(d)(7)(B)
CFR Citation: 40 CFR 63.

Abstract: On February 16, 2012, EPA
promulgated National Emission
Standards for Hazardous Air Pollutants for
Coal- and Oil-fired Electric Utility
Steam Generating Units (77 FR 9304).
The rule (40 CFR part 63, subpart
UUUUUU), commonly referred to as the
Mercury and Air Toxics Standards (MATS),
includes standards to control
hazardous air pollutant (HAP) emissions
from new and existing coal- and oil-
fired electric utility steam generating
units (EGUs) located at both major and
area sources of HAP emissions. There
have been several regulatory actions
regarding MATS since February 2012,
including a May 22, 2020, action that
completed a reconsideration of the
appropriate and necessary finding for
MATS and finalized the residual risk
and technology review (RTR) conducted
for the Coal- and Oil-Fired EGU source
category regulated under MATS (85 FR
31286). The Biden Administration’s
Executive Order 13990, Protecting
Public Health and the Environment and
Restoring Science To Tackle the Climate
Crisis, “directs all executive
departments and agencies (agencies) to
immediately review and, as appropriate
and consistent with applicable law, take
action to address the promulgation of
Federal regulations and other actions
during the last 4 years that conflict with
these important national objectives, and
to immediately commence work to
confront the climate crisis.” Section
2(a)(iv) of the Executive Order
specifically directs that the
Administrator consider publishing, as
appropriate and consistent with
applicable law, a proposed rule
suspending, revising, or rescinding the
“National Emission Standards for
Hazardous Air Pollutants: Coal- and Oil-
Fired Electric Utility Steam Generating
Units—Reconsideration of
Supplemental Finding and Residual
Risk and Technology Review.” 85 FR
31286 (May 22, 2020). As directed by
Executive Order 13990, EPA will review
the May 22, 2020 final action and, under
this action, will take appropriate action
resulting from its review of the May
2020 finding that it is not appropriate
and necessary to regulate coal- and oil-
fired EGU’s under Clean Air Act section
112. Results of EPA’s review of the May
2020 RTR will be presented in a
separate action (RIN 2060–AV53).

Statement of Need: As directed by
Executive Order 13990, EPA has
completed its review of the May 2020
finding that it is not appropriate and
necessary to regulate coal- and oil-fired
EGUs under Clean Air Act section 112.
EPA will issue the results of the review
in a notice of proposed rulemaking and
will solicit comment on the resulting
finding.

Summary of Legal Basis: CAA section
112, 42 U.S.C. 7412, provides the legal
framework and basis for regulatory
actions addressing emissions of
hazardous air pollutants from stationary
sources.

Alternatives: Two bases for the
appropriate and necessary
determination, one preferred and one
alternative, are put forth in the proposed
rulemaking.

Anticipated Cost and Benefits: There
are no anticipated costs or benefits
because there are no regulatory
amendments or impacts associated with
review of the appropriate and necessary
finding.

Risks: There are no anticipated risks
because there are no regulatory
amendments or impacts associated with
review of the appropriate and necessary
finding.

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Regulatory Flexibility Analysis
Required: Undetermined.

Government Levels Affected: None.
Additional Information: EPA—HQ—
OAR–2018–0794.

Sectors Affected: 921150 American
Indian and Alaska Native Tribal
Governments; 221122 Electric Power
Distribution; 221112 Fossil Fuel Electric
Power Generation.

URL For More Information: ttps://
www.epa.gov/mats/regulatory-actions-
final-mercury-and-air-toxics-standards-
mats-power-plants.

Agency Contact: Nick Hutson,
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Office of Air and Radiation, 109 T.W.
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Melanie King, Environmental
Protection Agency, Office of Air and
Radiation, 109 T.W. Alexander Drive,
Mail Code D243–01, Research Triangle
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Email: king.melanie@epa.gov.

Related RIN: Related to 2060–AT99.
RIN: 2060–AV12

EPA—OAR
150. Standards of Performance for New,
Reconstructed, and Modified Sources
and Emissions Guidelines for Existing
Sectors: Oil and Natural Gas Sector
Climate Review

Priority: Economically Significant.
Major under 5 U.S.C. 801.
Legal Authority: 42 U.S.C. 7411
CFR Citation: 40 CFR 60; 40 CFR 60
subpart OOOOa.

Legal Deadline: None.

Abstract: On January 20, 2021,
President Joe Biden issued an Executive
Order titled “Protecting Public Health
and the Environment and Restoring
Science to Tackle the Climate Crisis,”
which directs the EPA to take certain
actions by September 2021 to reduce
methane and volatile organic compound
(VOC) emissions in the oil and natural
gas sector. Specifically, the Executive
Order directs the EPA to review the new
source performance standards (NSPS)
issued in 2020 for the oil and gas sector
and, as appropriate and consistent with
applicable law, consider publishing for
notice and comment a proposed rule
suspending, revising, or rescinding the
NSPS. The Executive Order further
directs the EPA to consider proposing
(1) new regulations to establish
comprehensive NSPS for methane and
VOC emissions and (2) new regulations
to establish emission guidelines for
methane emissions from existing
operations in the oil and gas sector,
including from the exploration and
production, transmission, processing,
and storage segments. The purpose of
this action is to review the existing
NSPS and propose new standards as
necessary to meet the directives set forth
in the Executive Order, as well as to
propose new emission guidelines for
existing sources in the oil and gas
sector.

Statement of Need: Executive Order
13990, “Protecting Public Health and
the Environment and Restoring
Science to Tackle the Climate Crisis”. The
Executive Order directs the EPA to
consider proposing, by September 2021,
a rulemaking to reduce methane
emissions in the Oil and Natural Gas
sector category by suspending, revising,
or rescinding previously issued new
source performance standards. It also
instructs the EPA to consider proposing
new regulations to establish
comprehensive standards of
performance and emission guidelines for
methane and volatile organic
compound (VOC) emissions from existing operations in the oil and natural gas sector, including the exploration and production, processing, transmission and storage segments.

Summary of Legal Basis: Clean Air Act section 111(b) provides the legal framework for establishing greenhouse gas emission standards (in the form of limitations on methane and volatile organic compounds for new oil and natural gas sources. Clean Air Act section 111(d) provides the legal framework for establishing greenhouse gas emission standards (in the form of limitations on methane) for existing oil and natural gas sources.

Alternatives: The EPA has evaluated several options for new and existing sources and will propose and solicit comment on those options.

Anticipated Cost and Benefits: EPA is still evaluating the scope and associated costs, benefits and reductions associated with the forthcoming proposed rules.

Risks: EPA is still evaluating the scope and risks associated with the forthcoming proposed rules.

Timetable:

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Regulatory Flexibility Analysis

Required: Yes.

Small Entities Affected: Businesses.

Government Levels Affected: Underdetermined.

Energy Effects: Statement of Energy Effects planned as required by Executive Order 13211.

Additional Information:
Agency Contact: Karen Marsh, Environmental Protection Agency, Office of Air and Radiation, 109 T.W. Alexander Drive, Mail Code E143–01, Research Triangle Park, NC 27711, Phone: 919 541–1065, Email: marsh.karen@epa.gov.
Steve Fruh, Environmental Protection Agency, Office of Air and Radiation, 109 T.W. Alexander Drive, Mail Code E143–01, Research Triangle Park, NC 27711, Phone: 919 541–2937, Email: fruh.steve@epa.gov.

RIN: 2060–AV16

EPA—OAR

151. Review of Final Rule
Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act

Priority: Other Significant.

Unfunded Mandates: Undetermined.
Legal Authority: 42 U.S.C. 7401 et seq. CFR Citation: 40 CFR 63.1.
Legal Deadline: None.
Abstract: The final rule, Reclassification of Major Sources as Area Sources Under section 112 of the Clean Air Act (Major MACT to Area-MM2A final rule), was promulgated on November 19, 2020. (See 85 FR 73854) The MM2A final rule became effective on January 19, 2021. On January 20, 2021, President Biden issued Executive Order 13990 Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. The EPA has identified the MM2A final rule as an action being considered pursuant section (2)(a) of Executive Order 13990. Under this review, EPA, as appropriate and consistent with the Clean Air Act section 112, will publish for comment a notice of proposed rulemaking either suspending, revising, or rescinding the MM2A final rule.

Statement of Need: The EPA will issue a notice of proposed rulemaking of EPA’s review of the final rule Reclassification of Major Sources as Area Sources Under section 112 of the Clean Air Act (Major MACT to Area-MM2A final rule) pursuant Executive Order 13990. Pursuant section (2)(a) of Executive Order 13990 Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, the EPA is to review the MM2A final rule and as appropriate and consistent with the Clean Air Act section 112, to publish for comment a notice of proposed rulemaking either suspending, revising, or rescinding the MM2A final rule.

Summary of Legal Basis: The EPA issued a final rulemaking on November 19, 2020. The final MM2A rule provides that a major source cannot be reclassified to area source status at any time upon reducing its potential to emit (PTE) hazardous air pollutants (HAP) to below the major source thresholds (MST) of 10 tons per year (tpy) of any single HAP and 25 tpy of any combination of HAP. Pursuant section (2)(a) of Executive Order 13990 Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, the EPA is to review the MM2A final rule and as appropriate and consistent with the Clean Air Act section 112, to publish for comment a notice of proposed rulemaking either suspending, revising, or rescinding the MM2A final rule.

Alternatives: EPA will take comments on the review of the final MM2A and EPA’s proposed rulemaking either suspending, revising, or rescinding the MM2A final rule.

Anticipated Cost and Benefits: The anticipated costs and benefits of this action are to be determined.
Risks: The risks of this action are to be determined.

Timetable:

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Regulatory Flexibility Analysis

Required: Undetermined.

Government Levels Affected: Federal, Local, State, Tribal.

Federalism: Undetermined.

Additional Information:
Agency Contact: Elineth Torres, Environmental Protection Agency, Office of Air and Radiation, 109 T.W. Alexander Drive, Mail Code D205–02, Research Triangle Park, NC 27709, Phone: 919 541–4347, Email: torres.elineth@epa.gov.
Jodi Howard, Environmental Protection Agency, Office of Air and Radiation, E143–01, Research Triangle Park, NC 27711, Phone: 919 541–4991, Fax: 919 541–0246, Email: howard.jodi@epa.gov.

Related RIN: Related to 2060–AM75.
RIN: 2060–AV20

EPA—OAR

152. • Restrictions on Certain Uses of Hydrofluorocarbons Under Subsection (i) of the American Innovation and Manufacturing Act


Unfunded Mandates: Undetermined.
Legal Authority: 42 U.S.C. 7401 et seq. CFR Citation: 40 CFR 610.
Legal Deadline: None.
Abstract: EPA is considering a rule that will in part respond to petitions granted under subsection (i) of the American Innovation and Manufacturing (AIM) Act of 2020, enacted on December 27, 2020. Specifically, EPA is considering a rule restricting, fully, partially, or on a graduated schedule, the use of HFCs in sectors or subsectors including the refrigeration, air conditioning, aerosol, and foam sectors, and establishing recordkeeping and reporting requirements, and addressing other related elements of the AIM Act.

Statement of Need: This rule is required to meet the statutory provisions of subsection (i) of the American Innovation and Manufacturing (AIM) Act of 2020.

Summary of Legal Basis: The American Innovation and
Manufacturing (AIM) Act, enacted on December 27, 2020, provides EPA new authorities to address hydrofluorocarbons (HFCs) in three main areas: Phasing down the production and consumption of listed HFCs, maximizing reclamation and minimizing releases of these HFCs and their substitutes in equipment (e.g., refrigerators and air conditioners), and facilitating the transition to next-generation technologies by restricting the use of HFCs in particular sectors or subsectors. Subsection (i) of the AIM Act provides that a person may petition EPA to promulgate a rule for the restriction on use of a regulated substance in a sector or subsector. The statute requires EPA to grant or deny a petition under not later than 180 days after the date of receipt of the petition. If EPA grants a petition under subsection (i), then the statute requires EPA to promulgate a final rule not later than two years after the date on which the EPA grants the petition. In carrying out a rulemaking or making a determination to grant or deny a petition, the statute requires EPA, to the extent practicable, to take into account specified factors.

**Alternatives:** The alternatives for establishing a subsection (i) rule are whether to restrict, fully, partially, or on a graduated schedule, the use of HFCs in sectors or subsectors.

**Anticipated Cost and Benefits:** The Agency will prepare a Regulatory Impact Analysis (RIA) to provide the public with estimated potential costs and benefits of this action.

**Risks:** EPA is still evaluating the scope and risks associated with a prospective rule.

### Timetable:

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#### Regulatory Flexibility Analysis

**Required:** No.

**Government Levels Affected:** Undetermined.

**Federalism:** Undetermined.

**International Impacts:** This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Additional Information:**

- **Agency Contact:** Joshua Shodeinde, Environmental Protection Agency, Office of Air and Radiation, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 564–7037, Email: shodeinde.joshua@epa.gov.
- **RIN:** 2060–AV46

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**EPA—OAR**

### 153. Review of the National Ambient Air Quality Standards for Particulate Matter

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Legal Authority:** 42 U.S.C. 7414 et seq.

**Clean Air Act CFR Citation:** 40 CFR 50.

**Legal Deadline:** None.

**Abstract:** Under the Clean Air Act Amendments of 1977, EPA is required to review and if appropriate revise the air quality criteria for the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) every 5 years. On December 18, 2020, EPA published a final decision retaining the NAAQS for particulate matter (PM), which was the subject of several petitions for reconsideration as well as petitions for judicial review. As directed in Executive Order 13990, “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,” signed by President Biden on January 20, 2021, EPA is undertaking a review of the decision to retain the PM NAAQS. Based on that review, EPA is undertaking a rulemaking to reconsider the December 18, 2020 decision because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act. As part of this reconsideration, EPA intends to develop an updated Integrated Science Assessment (ISA) and revised policy assessment to take into account the most up-to-date science on public health impacts of PM, and to engage with the Clean Air Scientific Advisory Committee (CASAC) and a newly constituted expert PM panel.

**Statement of Need:** Under the Clean Air Act Amendments of 1977, EPA is required to review and if appropriate revise the air quality criteria and national ambient air quality standards (NAAQS) every 5 years. On December 18, 2020, EPA published a final rule retaining the NAAQS for particulate matter, without revision. On June 10, 2021, EPA announced that it is reconsidering the December 2020 decision on the air quality standards for PM.

**Summary of Legal Basis:** Under the Clean Air Act Amendments of 1977, EPA is required to review and if appropriate revise the air quality criteria and the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) every 5 years.

**Alternatives:** The main alternative for the Administrator’s decision on the review of the national ambient air quality standards for particulate matter is whether to retain or revise the existing standards.

**Anticipated Cost and Benefits:** The Clean Air Act makes clear that the economic and technical feasibility of attaining standards are not to be considered in setting or revising the NAAQS, although such factors may be considered in the development of state plans to implement the standards. Accordingly, when the Agency proposes revisions to the standards, the Agency prepares a Regulatory Impact Analysis (RIA) to provide the public with illustrative estimates of the potential costs and health and welfare benefits of attaining the revised standards.

**Risks:** The reconsideration will build on the review completed in 2020, which included the preparation by EPA of an Integrated Review Plan, an Integrated Science Assessment, and also a Policy Assessment, which includes a risk/ exposure assessment, with opportunities for review by the EPA’s Clean Air Scientific Advisory Committee (CASAC) and the public. These documents informed the Administrator’s final decision to retain the PM standards in 2020. As a part of the reconsideration, EPA will prepare an updated Policy Assessment and a Supplement to the Integrated Science Assessment, which will be reviewed at a public meeting by the CASAC. These documents will inform the Administrator’s proposed decisions on whether to revise the PM NAAQS, and will take into consideration these documents, CASAC advice, and public comment on the proposed decision.

### Timetable:

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#### Regulatory Flexibility Analysis

**Required:** No.

**Government Levels Affected:** None.

**Federalism:** Undetermined.

**Additional Information:**

- **Agency Contact:** Karen Wesson, Environmental Protection Agency, Office of Air and Radiation, 109 T.W. Alexander Drive, Mail Code C504–06, Research Triangle Park, NC 27711, Phone: 919 541–3515, Email: wesson.karen@epa.gov.
- **Nicole Hagan, Environmental Protection Agency, Office of Air and Radiation, 109 T.W. Alexander Drive, Mail Code C504–06, Research Triangle Park, NC 27709, Phone: 919 541–3153, Email: hagan.nicole@epa.gov.**
Program and Other Exemptions Under Minimum Risk Pesticide Listing

154. Pesticides; Modification to the Proposed Rule Stage

(OCSPP)

AND POLLUTION PREVENTION

bursad and focus EPA resources on effort is intended to reduce regulatory and development of a proposed rule. considering the public input received such as peat when used in septic pesticidal substances for exemption, exemptions or adding new classes of Agency evaluates the potential to focus our resources on pesticides that to pose little or no risk, and allows EPA to focus on pesticides that pose greater risk to humans and the environment. In April 2021, EPA issued an advance notice of proposed rulemaking (ANPRM) soliciting public comments and suggestions about the petition process for exemptions regarding pesticides from registration and other requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), where the pesticides are determined to be of a character unnecessary to be subject to regulation under FIFRA. The Agency is considering streamlining the petition process and revisions to how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions, state implementation of the minimum risk program and the need for any future exemptions or modifications to current exemptions. EPA is also sought comment on whether the Agency should consider amending existing exemptions or adding new classes of pesticidal substances for exemption, such as peat when used in septic filtration systems. EPA is currently considering the public input received and development of a proposed rule. Statement of Need: This rulemaking effort is intended to reduce regulatory burdens and focus EPA resources on pesticide products that have risks to public health or the environment by streamlining the petition process used to seek such exemptions; revising how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions and state implementation of the minimum risk program; and considering the need for any future exemptions or modifications to current exemptions.

Summary of Legal Basis: Exemptions to the requirements of FIFRA are issued under the authority of FIFRA section 25(b). Eligible products may be exempt from, among other things, registration requirements under FIFRA section 3. Alternatives: In considering a streamlined petition process and other improvements, EPA intends to identify and evaluate alternative policies that facilitate the effective and efficient identification of pesticides products that could be exempt from registration and other requirements under FIFRA. Anticipated Cost and Benefits: EPA intends to consider the costs and benefits of proposed improvements during the development of the proposed rule.

RIN: 2060–AV52

EPA—OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION (OCSPP)

Proposed Rule Stage

154. Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions Under FIFRA Section 25(b)

Priority: Other Significant.

Legal Authority: 7 U.S.C. 136(w)

Federal Insecticide Fungicide and Rodenticide Act

CFR Citation: 40 CFR 152.

Legal Deadline: None.

Abstract: Under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA has determined that certain “minimum risk pesticides” pose little to no risk to human health or the environment, and has exempted them from registration and other requirements under FIFRA. In 1996, EPA created a regulatory list of minimum risk active and inert ingredients in 40 CFR 152.25. Such an exemption reduces the cost and regulatory burdens on businesses and the public for those pesticides deemed to pose little or no risk, and allows EPA to focus our resources on pesticides that pose greater risk to humans and the environment. In April 2021, EPA issued an advance notice of proposed rulemaking (ANPRM) soliciting public comments and suggestions about the petition process for exemptions regarding pesticides from registration and other requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), where the pesticides are determined to be of a character unnecessary to be subject to regulation under FIFRA. The Agency is considering streamlining the petition process and revisions to how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions, state implementation of the minimum risk program and the need for any future exemptions or modifications to current exemptions. EPA is also sought comment on whether the Agency should consider amending existing exemptions or adding new classes of pesticidal substances for exemption, such as peat when used in septic filtration systems. EPA is currently considering the public input received and development of a proposed rule. Statement of Need: This rulemaking effort is intended to reduce regulatory burdens and focus EPA resources on pesticide products that have risks to public health or the environment by streamlining the petition process used to seek such exemptions; revising how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions and state implementation of the minimum risk program; and considering the need for any future exemptions or modifications to current exemptions.

Summary of Legal Basis: Exemptions to the requirements of FIFRA are issued under the authority of FIFRA section 25(b). Eligible products may be exempt from, among other things, registration requirements under FIFRA section 3. Alternatives: In considering a streamlined petition process and other improvements, EPA intends to identify and evaluate alternative policies that facilitate the effective and efficient identification of pesticides products that could be exempt from registration and other requirements under FIFRA. Anticipated Cost and Benefits: EPA intends to consider the costs and benefits of proposed improvements during the development of the proposed rule. Risks: This procedural rule is not intended to address identified risks, and, by definition, will only involve pesticides products identified as having minimal risk.

Timetable:

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Regulatory Flexibility Analysis

Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Additional Information:

Sectors Affected: 624410 Child Day Care Services; 424210 Drugs and Druggists’ Sundries Merchant Wholesalers; 561710 Exterminating and Post Control Services; 424910 Farm Supplies Merchant Wholesalers; 561730 Landscaping Services; 423120 Motor Vehicle Supplies and New Parts Merchant Wholesalers; 444220 Nursery, Garden Center, and Farm Supply Stores; 311119 Other Animal Food Manufacturing; 444210 Outdoor Power Equipment Stores; 325320 Pesticide and Other Agricultural Chemical Manufacturing; 926150 Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors; 562901 Septic Tank and Related Services; 221320 Sewage Treatment Facilities; 238910 Site Preparation Contractors; 325611 Soap and Other Detergent Manufacturing; 611620 Sports and Recreation Instruction; 445110 Supermarkets and Other Grocery (except Convenience) Stores.


Agency Contact: Sara Kemme, Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, 1200 Pennsylvania Avenue NW, Mail Code 7101M, Washington, DC 20460, Phone: 202 566–1217, Email: kemme.sara@epa.gov.

Cameo Smoot, Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, 1200 Pennsylvania Avenue NW, Mail Code 7101M, Washington, DC 20460, Phone: 202 566–1207, Email: smooot.cameo@epa.gov.

RIN: 2070–AK55

EPA—OCSPP

155. Cyclic Aliphatic Bromide Cluster (HBCD); Rulemaking Under TSCA Section 6(a)


Unfunded Mandates: Undetermined.

Legal Authority: 15 U.S.C. 2605 Toxic Substances Control Act

CFR Citation: 40 CFR 751.

Legal Deadline: NPRM, Statutory, September 15, 2021, TSCA section 6(c). Final, Statutory, September 15, 2022, TSCA section 6(c).

Abstract: Section 6 of the Toxic Substances Control Act (TSCA) requires EPA to address unreasonable risks of injury to health or the environment that the Administrator has determined are presented by a chemical substance under the conditions of use. Following a risk evaluation for cyclic aliphatic bromide cluster (HBCD) carried out under the authority of the TSCA section 6, EPA initiated rulemaking to address unreasonable risks of injury to health and the environment identified in the final risk evaluation. EPA’s risk evaluation for HBCD, describing the conditions of use and presenting EPA’s determinations of unreasonable risk, is in docket EPA–HQ–OPPT–2019–0237, with additional information in docket EPA–HQ–OPPT–2016–0735.

Statement of Need: This rulemaking is needed to address the unreasonable risk of the Cyclic Aliphatic Bromide Cluster (or, “HBCD”) identified in a risk evaluation completed under TSCA section 6(b). EPA reviewed the exposures and hazards of HBCD uses, the magnitude of risk, exposed populations, severity of the hazard, uncertainties, and other factors. EPA
sought input from the public and peer reviewers as required by TSCA and associated regulations.

Summary of Legal Basis: In accordance with TSCA section 6(a), if EPA determines in a final risk evaluation completed under TSCA 6(b) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Agency must issue regulations requiring one or more of the following actions to the extent necessary so that the chemical substance no longer presents an unreasonable risk: (1) Prohibit or otherwise restrict manufacture, processing, or distribution in commerce; (2) Prohibit or otherwise restrict for a particular use or above a set concentration; (3) Require minimum warnings and instructions with respect to use, distribution in commerce, or disposal; (4) Require recordkeeping or testing; (5) Prohibit or regulate any manner or method of commercial use; (6) Prohibit or regulate any manner or method of disposal; and/or (7) Direct manufacturers or processors to give notice of the unreasonable risk to distributors and replace or repurchase products if required.

Alternatives: There are no non-regulatory alternatives to this rulemaking. TSCA section 6(a) requires EPA to address by rule chemical substances that the Agency determines present unreasonable risk upon completion of a final risk evaluation. As required under TSCA section 6(c), EPA will consider one or more primary alternative regulatory actions as part of the development of a proposed rule.

Anticipated Cost and Benefits: EPA will prepare a regulatory impact analysis as the Agency develops the proposed rule.

Risks: As EPA determined in the TSCA section 6(b) risk evaluation, HBCD presents unreasonable risks to human health and the environment. EPA must issue regulations so that this chemical substance no longer presents an unreasonable risk. For more information, visit: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-existing-chemicals-under-tsca.

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Regulatory Flexibility Analysis
Required: Undetermined.
Designating PFOA and PFOS as CERCLA hazardous substances will require reporting of releases of PFOA and PFOS that meet or exceed the reportable quantity assigned to these substances. This will enable Federal, State Tribal, and local authorities to collect information regarding the location and extent of releases.

Statement of Need: Designating PFOA and PFOS as CERCLA hazardous substances will require reporting of releases of PFOA and PFOS that meet or exceed the reportable quantity assigned to these substances. This will enable Federal, State, Tribal and local authorities to collect information regarding the location and extent of releases.

Summary of Legal Basis: No aspect of this action is required by statute or court order.

Alternatives: The Agency identified through the 2019 PFAS Action Plan that one of the goals was to designate PFOA and PFOS as hazardous substances. EPA determined that we have enough information to propose this designation.

Anticipated Cost and Benefits: The EPA is analyzing the potential costs and benefits associated with this action with respect to the reporting of any release of the subject hazardous substances to the Federal, State, and local authorities. Currently EPA expects to estimate lower and upper-bound reporting cost scenarios.

Risks: This is a reporting rule and will enable Federal, State, Tribal and local authorities to collect information regarding the location and extent of releases.

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Regulatory Flexibility Analysis Required: No.

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations.

Government Levels Affected: Federal, Local, State, Tribal.

Additional Information:

Sectors Affected: 325998 All Other Miscellaneous Chemical Product and Preparation Manufacturing; 327110 Electroplating, Plating, Polishing, Anodizing, and Coloring; 281690 Other Protection, Force Protection, and Industrial Defense; 322100 Chemical Manufacturing; 322110 Paper (except Newsprint) Mills; 322120 Paperboard Mills; 424710 Petroleum Bulk Stations and Terminals; 324110 Petroleum Refineries; 325992 Photographic Film, Paper, Plate, and Chemical Manufacturing; 562212 Solid Waste Landfill.

Agency Contact: Michelle Schutz, Environmental Protection Agency, Office of Land and Emergency Management, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 703 603–8708, Email: schutz.michelle@epa.gov.

RIN: 2050–AH90

EPA—OLEM

158. Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Legacy Surface Impoundments

Priority: Other Significant.

Legal Authority: 42 U.S.C. 6906; 42 U.S.C. 6907; 42 U.S.C. 6912(a); 42 U.S.C. 6944; 42 U.S.C. 6945(c)

CFR Citation: 40 CFR 257.

Legal Deadline: None.

Abstract: On April 17, 2015, the Environmental Protection Agency (EPA or the Agency) promulgated national minimum criteria for existing and new coal combustion residuals (CCR) landfills and existing and new CCR surface impoundments. On August 21, 2018 the D.C. Circuit Court of Appeals issued its opinion in the case of Utility Solid Waste Activities Group, et al v. EPA, which vacated and remanded the provision that exempted inactive impoundments at inactive facilities from the CCR rule. The EPA is developing regulations to implement this part of the court decision for inactive CCR surface impoundments at inactive utilities, or “legacy units”. This proposal may include adding a new definition for legacy CCR surface impoundments. The EPA may also propose to require such legacy CCR surface impoundments to follow existing regulatory requirements for fugitive dust, groundwater monitoring, and closure, or other technical requirements.

Statement of Need: On April 17, 2015, the EPA finalized national regulations to regulate the disposal of Coal Combustion Residuals (CCR) as solid waste under subtitle D of the Resource Conservation and Recovery Act (RCRA) (2015 CCR final rule). In response to the Utility Solid Waste Activities Group v. EPA decision, this proposed rulemaking, if finalized, would bring inactive surface impoundments at inactive facilities (legacy surface impoundments) into the regulated universe.
Summary of Legal Basis: No statutory or judicial deadlines apply to this rule. The EPA is taking this action in response to an August 21, 2018 court decision that vacated and remanded the provision that exempted inactive impoundments at inactive electric utilities from the 2015 CCR final rule. The proposed rule would be established under the authority of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HWSPA) and the Water Infrastructure Improvements for the Nation Act of 2016.

Alternatives: The Agency issued an advance notice of proposed rulemaking (ANPRM) on October 14, 2020 (85 FR 65015), which included public notice and opportunity for comment on this effort. We have not identified at this time any significant alternatives for analysis.

Anticipated Cost and Benefits: The Agency will determine anticipated costs and benefits later as it is currently too early in the process.

Risks: The Agency will estimate the risk reductions and impacts later as it is currently too early in the process.

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Regulatory Flexibility Analysis Required: Undetermined.

Government Levels Affected: Federal, State.


Agency Contact: Frank Behan, Environmental Protection Agency, Office of Land and Emergency Management, Mail Code 5304T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 566–1730, Email: behan.frank@epa.gov.

Michelle Lloyd, Environmental Protection Agency, Office of Land and Emergency Management, Mail Code 5304T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 566–0560, Email: long.michelle@epa.gov.

RIN: 2050–AH14

EPA—OLEM

159. Accidental Release Prevention Requirements: Risk Management Program Under the Clean Air Act; Retrospection


Unfunded Mandates: Undetermined. Legal Authority: 42 U.S.C. 7412 Clean Air Act

CFR Citation: 40 CFR 68.

Legal Deadline: None.

Abstract: The Environmental Protection Agency (EPA) is considering revising the Risk Management Program (RMP) regulations, which implement the requirements of section 112(r)(7) of the 1990 Clean Air Act amendments. The RMP requires facilities that use listed extremely hazardous substances above specified threshold quantities to develop a Risk Management Plan. The EPA is reviewing the RMP rule in accordance with Executive Order 13990: Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis, which directs federal agencies to review existing regulations and take action to address the Administration’s priorities, including bolstering resilience to the impacts of climate change and prioritizing environmental justice.

Statement of Need: On January 13, 2017, the EPA published a final RMP rule (2017 Amendments) to prevent and mitigate the effect of accidental releases of hazardous chemicals from facilities that use, manufacture, and store them. The 2017 Amendments were a result of Executive Order 13650, Improving Chemical Facility Safety and Security, which directed EPA (and several other federal agencies) to, among other things, modernize policies, regulations, and standards to enhance safety and security in chemical facilities. The 2017 Amendments rule contained various new provisions applicable to RMP-regulated facilities addressing prevention program elements, emergency coordination with local responders, and information availability to the public. EPA received three petitions for reconsideration of the 2017 Amendments rule under CAA section 307(d)(7)(B). On December 19, 2019, EPA promulgated a final RMP rule (2019 Revisions) that acts on the reconsideration. The 2019 Revisions rule repealed several major provisions of the 2017 Amendments and retained other provisions with modifications.

On January 20, 2021, Executive Order 13990, Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis (E.O. 13990), directed federal agencies to review existing regulations and take action to address priorities established by the new administration including bolstering resilience to the impact of climate change and prioritizing environmental justice. The EPA is considering developing a regulatory action to revise the current RMP regulations. The proposed rule would address the administration’s priorities and focus on regulatory revisions completed since 2017. The proposed rule would also expect to contain a number of proposed modifications to the RMP regulations based in part on stakeholder feedback received from RMP public listening sessions held on June 16 and July 8, 2021.

Summary of Legal Basis: The CAA section 112(r)(7)(A) authorizes the EPA Administrator to promulgate accidental release prevention, detection, and correction requirements, which may include monitoring, record keeping, reporting, training, vapor recovery, secondary containment, and other design, equipment, work practice, and operational requirements. The CAA section 112(r)(7)(B) authorizes the Administrator to promulgate reasonable regulations and appropriate guidance to provide, to the greatest extent practicable, for the prevention and detection of accidental releases of regulated substances and for response to such releases by the owners or operators of the sources of such releases.

Alternatives: The EPA currently plans to prepare a notice of proposed rulemaking that would provide the public an opportunity to comment on the proposal, and any regulatory alternatives that may be identified within the preamble to the proposed rulemaking.

Anticipated Cost and Benefits: Costs may include the burden on regulated entities associated with implementing new or revised requirements including program implementation, training, equipment purchases, and recordkeeping, as applicable. Some costs could also accrue to implementing agencies and local governments, due to new or revised provisions associated with emergency response. Benefits will result from avoiding the harmful accident consequences to communities and the environment, such as deaths, injuries, and property damage, environmental damage, and from mitigating the effects of releases that may occur. Similar benefits will accrue to regulated entities and their employees.

Risks: The proposed action would address the risks associated with accidental releases of listed regulated...
toxic and flammable substances to the air from stationary sources. Substances regulated under the RMP program include highly toxic and flammable substances that can cause deaths, injuries, property and environmental damage, and other on- and off-site consequences if accidentally released. The proposed action would reduce these risks by potentially making accidental releases less likely, and by mitigating the severity of releases that may occur. The proposed action would not address the risks of non-accidental chemical releases, accidental releases of non-regulated substances, chemicals released to other media, and air releases from mobile sources.

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**Regulatory Flexibility Analysis**

Required: Undetermined.

**Government Levels Affected:**

Undetermined.

**Federalism:** Undetermined.

**Additional Information:**

- **Sectors Affected:** 42469 Other Chemical and Allied Products Merchant Wholesalers; 22131 Water Supply and Irrigation Systems; 49313 Farm Product Warehousing and Storage; 11511 Support Activities for Crop Production; 221112 Fossil Fuel Electric Power Generation; 31152 Ice Cream and Frozen Dessert Manufacturing; 311612 Meat Processed from Carnasses; 311411 Frozen Fruit, Juice, and Vegetable Manufacturing; 4931 General Warehousing and Storage; 42491 Farm Supplies Merchant Wholesalers; 49312 Refrigerated Warehousing and Storage; 32519 Other Basic Organic Chemical Manufacturing; 211112 Natural Gas Liquid Extraction; 49319 Other Warehousing and Storage; 322 Paper Manufacturing; 22132 Sewage Treatment Facilities; 325 Chemical Manufacturing; 311511 Fluid Milk Manufacturing; 32411 Petroleum Refineries; 311615 Poultry Processing; 42471 Petroleum Bulk Stations and Terminals; 311 Food Manufacturing.

**Agency Contact:** Deanne Grant, Environmental Protection Agency, Office of Land and Emergency Management, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 564–1096, Email: grant.deanne@epa.gov.


**EPA—OFFICE OF WATER (OW)**

**Proposed Rule Stage**

**160. Federal Baseline Water Quality Standards for Indian Reservations**

**Priority:** Other Significant.

**Legal Authority:** 33 U.S.C. 1313(c)(4)(B)

**CFR Citation:** 40 CFR 131.

**Legal Deadline:** None.

**Abstract:** EPA is developing a proposed rule to establish tribal baseline water quality standards (WQS) for waters on Indian reservations that do not have WQS under the Clean Water Act (CWA). Less than 20 percent of reservations have EPA-approved tribal WQS. Promulgating baseline WQS would address this longstanding gap and provide more scientific rigor and regulatory certainty to National Pollutant Discharge Elimination System (NPDES) permits for discharges to these waters. Consistent with EPA regulations, the baseline WQS would include designated uses, water quality criteria to protect those uses, and antidegradation policies to protect high quality waters. EPA initiated tribal consultation on June 15th, 2021 and will be engaged in coordination and consultation with tribes throughout the consultation period, which ends September 13th, 2021. EPA welcomes consultation with tribes both during and after the consultation period. EPA plans to propose this rule by early 2022 and to finalize by early 2023.

**Statement of Need:** The federal government has recognized 574 tribes. More than 300 of these tribes have reservation lands such as formal reservations, Pueblos, and informal reservations (i.e., lands held in trust by the United States for tribal governments that are not designated as formal reservations) and are eligible to administer a WQS program. Only 75 tribes, out of over 300 tribes with reservations, currently have such TAS authorization to administer a WQS program. Of those 75 tribes, only 46 tribes to date have adopted WQS and submitted them to EPA for review and approval under the CWA. As a result, 50 years after enactment of the CWA, over 80% of Indian reservations do not have this foundational protection expected by Congress as laid out in the CWA for their waters. This lack of CWA-effective WQS for the waters of more that 1750 Indian reservations is a longstanding gap in human health and environmental protections, given that WQS are central to implementing the water quality framework of the CWA. Although it is EPA’s preference for tribes to obtain TAS and develop WQS tailored to the tribes’ individual environmental goals and reservation waters, EPA’s promulgation of baseline WQS would serve to safeguard water quality until tribes obtain TAS and adopt and administer CWA WQS themselves.

**Summary of Legal Basis:** While CWA section 303 clearly contemplates WQS for all waters of the United States, it does not explicitly address WQS for Indian country waters where tribes lack CWA-effective WQS. Under CWA section 303(a) states were required to adopt WQS for all interstate and intrastate waters. Where a state does not establish such standards, Congress directed EPA to do so under the CWA section 303(b). These provisions are consistent with Congress’ design of the CWA as a general statute applying to all waters of the United States, including those within Indian country. Several provisions of the CWA provide EPA with the authority to propose this rule. Section 501(a) of the CWA provides that the Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter. In Indian country waters where tribes are not yet authorized to establish WQS and where states lack jurisdiction to do the same, EPA is responsible for implementing section 303(c) of the CWA. Section 303(c)(4)(B) of the CWA provides that the Administrator shall promptly prepare and publish proposed regulations setting forth a revised or new water quality standard for the navigable waters involved in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. In 2001 the EPA Administrator made an Administrator’s Determination that new or revised WQS are necessary for certain Indian country waters.

**Alternatives:** To be determined.

**Anticipated Cost and Benefits:** To be determined.

**Risks:** To be determined.

**Timetable:**

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**Regulatory Flexibility Analysis**

Required: No.

**Small Entities Affected:** No.

**Government Levels Affected:** Federal, State, Tribal.
Government Levels Affected: Undetermined.
Federalism: Undetermined.
Additional Information:
Agency Contact: Lauren Kasparek, Environmental Protection Agency, Office of Water, Mail Code 4305T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 566–1433, Email: kasparek.lauren@epa.gov.
Related RIN: Related to 2040–AF86.
RIN: 2040–AG12

EPA—OW
162. Revised Definition of “Waters of the United States”—Rule 1

Unfunded Mandates: Undetermined.
Legal Authority: 33 U.S.C. 1251
CFR Citation: 40 CFR 120.1.
Legal Deadline: None.
Abstract: In April 2020, the EPA and the Department of the Army (the agencies) published the Navigable Waters Protection Rule (NWPR) that revised the previously codified definition of “waters of the United States” (85 FR 22250, April 21, 2020). The agencies are now initiating this new rulemaking process that restores the regulations in place prior to the 2015 “Clean Water Rule: Definition of ‘Waters of the United States’ ” (80 FR 37054, June 29, 2015), updated to be consistent with relevant Supreme Court decisions. The agencies intend to consider further revisions in a second rule in light of additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

Statement of Need: To be determined.

Summary of Legal Basis: To be determined.

Alternatives: To be determined.

Anticipated Cost and Benefits: To be determined.

Risks: To be determined.

Timetable:

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Regulatory Flexibility Analysis
Required: No.

EPA—OW
163. Revised Definition of ‘Waters of the United States’—Rule 2

Priority: Other Significant.
Legal Authority: 33 U.S.C. 1251
CFR Citation: 40 CFR 120.1.
Legal Deadline: None.
Abstract: The EPA and the Department of the Army (the agencies’) intend to pursue a second rule defining “Waters of the United States” to consider further revisions to the agencies’ first rule (RIN 2040–AG13) which proposes to restore the regulations in place prior to the 2015 “Clean Water Rule: Definition of ‘Waters of the United States’ ” (80 FR 37054, June 29, 2015), updated to be consistent with relevant Supreme Court Decisions. This second rule proposes to include revisions reflecting on additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule.

Statement of Need: The agencies intend to pursue a second rule defining waters of the United States to consider
further revisions to the agencies’ first rule which proposes to restore the regulations in place prior to the 2015 WOTUS rule, updated to be consistent with relevant Supreme Court Decisions. This second rule proposes to include revisions reflecting on additional stakeholder engagement and implementation considerations, scientific developments, and environmental justice values. This effort will also be informed by the experience of implementing the pre-2015 rule, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule. Summary of Legal Basis: The Clean Water Act (33 U.S.C. 1251 et seq.).

Alternatives: To be determined.

Anticipated Cost and Benefits: To be determined.

Risks: To be determined.

Timetable:

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Regulatory Flexibility Analysis
Required: No.

Government Levels Affected: Undetermined.

Additional Information:
Agency Contact: Whitney Beck, Environmental Protection Agency, Office of Water, Mail Code 4504T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 566–2553, Email: beck.whitney@epa.gov.

RIN: 2040–AG19

EPA—OFFICE OF AIR AND RADIATION (OAR)

Final Rule Stage


Priority: Economically Significant.

Major under 5 U.S.C. 801.

Legal Authority: 42 U.S.C. 7411 Clean Air Act; 42 U.S.C. 7401 CFR Citation: 40 CFR 85.1401; 40 CFR 86; 40 CFR 600.001.

Legal Deadline: None.


Summary of Legal Basis: CAA section 202 (a).

Alternatives: EPA requested comment to address alternative options in the proposed rule.

Anticipated Cost and Benefits: Compliance with the standards would impose reasonable costs on manufacturers. The proposed revised standards would result in significant benefits for public health and welfare, primarily through substantial reductions in both GHG emissions and fuel consumption and associated fuel costs paid by drivers.

Risks: EPA will evaluate the risks of this rulemaking.

Timetable:

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Regulatory Flexibility Analysis
Required: Undetermined.


Sectors Affected: 335312 Motor and Generator Manufacturing; 336111 Automobile Manufacturing; 811111 General Automotive Repair; 811112 Automotive Exhaust System Repair; 811198 All Other Automotive Repair and Maintenance.

Agency Contact: Tad Wyisor, Environmental Protection Agency, Office of Air and Radiation, USEPA, Ann Arbor, MI 48105, Phone: 734 214–4332, Fax: 734 214–4816, Email: wyisor.tad@epa.gov.

Jessica Mroz, Environmental Protection Agency, Office of Air and Radiation, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 564–1094, Email: mroz.jessica@epa.gov.

RIN: 2060–AV13

EPA—OFFICE OF LAND AND EMERGENCY MANAGEMENT (OLEM)

Final Rule Stage

165. Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Federal CCR Permit Program

Priority: Other Significant.


Legal Deadline: None.

Abstract: The Water Infrastructure Improvements for the Nation (WIIN) Act established a new coal combustion residual (CCR) regulatory structure under which states may seek approval from the Environmental Protection Agency (EPA) to operate a permitting program that would regulate CCR facilities within their state; if approved, the state program would operate in lieu of the federal requirements. The WIIN Act requires that such state programs must ensure that facilities comply with either the federal regulations or with state requirements that the EPA has determined are “at least as protective as” the federal regulations. Furthermore, the WIIN Act established a requirement for the EPA to establish a federal permit program for the disposal of CCR in Indian Country and in “nonparticipating” states, contingent upon Congressional appropriations. In March 2018 (Pub. L. 115–141) and March 2019 (Pub. L. 116–6), Congress appropriated funding for federal CCR permitting. The final rule would establish a new federal permitting program for disposal of CCR. The potentially regulated universe is limited to facilities with CCR disposal units subject to regulation under 40 CFR part 257 subpart D, which are located in Indian Country and in nonparticipating states. Remaining CCR facilities would be regulated by an approved state program and would not be subject to federal permitting requirements.

Statement of Need: The Water Infrastructure Improvements for the Nation (WIIN) Act established a new CCR regulatory structure under which states may seek approval from the EPA to operate a permitting program that would operate in lieu of the federal requirements. Furthermore, the WIIN Act established a requirement for the EPA to establish a federal permit program for the disposal of CCR in Indian Country and in nonparticipating states, contingent upon Congressional appropriations. In March 2018, Congress appropriated funding for federal CCR permitting.

Summary of Legal Basis: No statutory or judicial deadlines apply to this rule. This rule would be established under the authority of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HWSA) and the Water Infrastructure Improvements for the Nation Act of 2016.
Alternatives: The Agency provided public notice and opportunity for comment on the proposal to establish a federal permit program. The proposal included procedures for issuing permits. Substantive requirements are addressed in the existing CCR regulations (40 CFR part 257 subpart D). Alternatives considered in the proposal included approaches to tiering initial application deadlines (e.g., by risks presented due to unit stability or other factors, such as leaking units) and procedures for permit by rule or issuance of general permits as an alternative to individual permits.

Anticipated Cost and Benefits: Costs and benefits of the February 20, 2020 proposal were presented in the Regulatory Impact Analysis (RIA) supporting the proposed rule. The EPA estimated that the net effect of proposed revisions would result in an estimated annual cost of this proposal is a cost increase of approximately $136,312. This cost increase is composed of approximately $135,690 in annualized labor costs and $622 in capital or operation and maintenance costs.

Risks: The proposal to establish a federal CCR permit program is not expected to impact the overall risk conclusions discussed in the 2015 CCR Rule. The proposal would establish procedural requirements for issuance of permits which would generally not establish substantive requirements affecting environmental risk.

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: Businesses.
Government Levels Affected: Federal, Local, Tribal.

EPA—OLEM

Priority: Other Significant.
Legal Authority: 42 U.S.C. 6906; 42 U.S.C. 6907; 42 U.S.C. 6912(a); 42 U.S.C. 6944; 42 U.S.C. 6945(c)
CFR Citation: 40 CFR 257.
Legal Deadline: None.
Abstract: On April 17, 2015, the Environmental Protection Agency (EPA) promulgated national minimum criteria for existing and new coal combustion residuals (CCR) landfills and existing and new CCR surface impoundments. On August 21, 2018, the D.C. Circuit Court of Appeals issued its opinion in the case of Utility Solid Waste Activities Group, et al v. EPA. On October 15, 2018, the court issued its mandate, vacating certain provisions of the 2015 final rule. On March 3, 2020, the EPA proposed a number of revisions and flexibilities to the CCR regulations. In particular, the EPA proposed the following revisions: (1) Procedures to allow facilities to request approval to use an alternate liner for CCR surface impoundments; (2) Two co-proposed options to allow the use of CCR during unit closure; (3) An additional closure option for CCR units being closed by removal of CCR; and (4) Requirements for annual closure progress reports. The EPA has since taken final action on one of the four proposed issues. Specifically, on November 12, 2020, the EPA issued a final rule that would allow a limited number of facilities to demonstrate to the EPA that based on groundwater data and the design of a particular surface impoundment, the unit has and will continue to have no probability of adverse effects on human health and the environment. (This final rule was covered under RIN 2050–AH11. See “Additional Information” section.) The present rulemaking would consider taking final action on the remaining proposed issues.

Statement of Need: On April 17, 2015, the EPA finalized national regulations to regulate the disposal of Coal Combustion Residuals (CCR) as solid waste under subtitle D of the Resource Conservation and Recovery Act (RCRA) (2015 CCR Rule). On March 3, 2020, the EPA proposed a number of revisions to the CCR regulations, the last in a set of four planned actions to implement the Water Infrastructure Improvements for the Nation (WIFIN) Act, respond to petitions for rulemaking, and apply lessons learned to ensure smoother implementation of the regulations.

Summary of Legal Basis: No statutory or judicial deadlines apply to this rule. This rule would be established under the authority of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HWSPA) and the Water Infrastructure Improvements for the Nation Act of 2016.

Alternatives: The Agency provided public notice and opportunity for comment on these issues associated with the closure of CCR surface impoundments. Each of these issues is fairly narrow in scope and we have not identified any significant alternatives for analysis.

Anticipated Cost and Benefits: Costs and benefits of the March 3, 2020 proposed targeted changes were presented in the Regulatory Impact Analysis (RIA) supporting the proposed rule. EPA estimated that the net effect of proposed revisions (excluding the one issue that EPA finalized on November 12, 2020) to be an annualized cost savings of between $37 million and $129 million when discounting at 7%. The RIA also qualitatively describes the potential effects of the proposal on two categories of benefits from the 2015 CCR Rule.

Risks: Key benefits of the 2015 CCR Rule included the prevention of future catastrophic failures of CCR surface impoundments, the protection of groundwater from contamination, the reduction of dust in communities near CCR disposal units and increases in the beneficial use of CCR. The average annual monetized benefits of the 2015 CCR Rule were estimated to be $232 million per year using a seven percent discount rate. For reasons discussed in the March 3, 2020 proposal, the EPA was unable to quantify or monetize the proposed rule’s incremental effect on human health and the environment using currently available data.

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Regulatory Flexibility Analysis
Required: No.
Small Entities Affected: Businesses.
Government Levels Affected: Federal, Local, State, Tribal.
for Unlined Surface Impoundments; Implementation of Closure. This action was split from 2050–AH11 after the March 3, 2020 NPRM (85 FR 12456) as two final rules would be developed based on the proposed rule. The November 12, 2020 final rule (85 FR 72506) mentioned in this abstract was covered under 2050–AH11.


Agency Contact: Jesse Miller, Environmental Protection Agency, Office of Land and Emergency Management, 1200 Pennsylvania Avenue NW, Mail Code 5304T, Washington, DC 20460, Phone: 202 566–0562, Email: miller.jesse@epa.gov.

Frank Behan, Environmental Protection Agency, Office of Land and Emergency Management, Mail Code 5304T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 566–1730, Email: behan.frank@epa.gov.

RIN: 2050–AH18

EPA—OFFICE OF WATER (OW)

Final Rule Stage

167. • Cybersecurity in Public Water Systems

Priority: Other Significant.

Legal Authority: 5 U.S.C. 553(b)(3)(A)

CFR Citation: 40 CFR 142.16; 40 CFR 142.2.

Legal Deadline: None.

Abstract: EPA is evaluating regulatory approaches to ensure improved cybersecurity at public water systems. EPA plans to offer separate guidance, training, and technical assistance to states and public water systems on cybersecurity. This action will provide regulatory clarity and certainty and promote the adoption of cybersecurity measures by public water systems.

Statement of Need: A cyber-attack can degrade the ability of a public water system to produce and distribute safe drinking water. The risk of a cyber-attack can be reduced through the adoption of cybersecurity best practices by public water systems. Sanitary surveys, which states, tribes, or the EPA typically conduct every 3 to 5 years on all public water systems, should include an evaluation of cybersecurity to identify significant deficiencies. EPA recognizes, however, that many states currently do not assess cybersecurity practices during public water system sanitary surveys. This action is necessary to convey to states that EPA interprets existing regulations for public water system sanitary surveys as including the possible identification of significant deficiencies in cybersecurity practices.

Summary of Legal Basis: The Administrative Procedure Act exempts interpretive rules from its notice and comment requirements, 5 U.S.C. 553(b)(3)(A). The term is not defined in the APA, but the Attorney General’s Manual on the APA, often considered to be akin to legislative history, describes them as “rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers.”

Alternatives: Provide guidance to states, tribes, and EPA on evaluating cybersecurity practices during public water system sanitary surveys without issuing an interpretive rule.

Anticipated Cost and Benefits: This action is an interpretation of existing responsibilities under current regulations. It establishes no new regulatory requirements and, hence, has no regulatory costs or benefits.

Risks: The purpose of this action is to reduce the risks associated with cyber-attacks on public water systems. Because this action is not establishing new regulatory requirements, EPA has not quantified costs and benefits for it. Accordingly, EPA has not estimated the current level of risk or the possible reduction in risk due to this action.

Timetable:

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Regulatory Flexibility Analysis Required: No.

Government Levels Affected: Undetermined.

Additional Information:


Agency Contact: Stephanie Flaharty, Environmental Protection Agency, Office of Water, 4601M, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 202 564–5072, Email: flaharty.stephanie@epa.gov.

RIN: 2040–AG20

EPA—OW

Long-Term Actions

168. National Primary Drinking Water Regulations for Lead and Copper: Regulatory Revisions


Unfunded Mandates: Undetermined.

Legal Authority: 42 U.S.C. 300f et seq. Safe Drinking Water Act

CFR Citation: 40 CFR 141; 40 CFR 142.

Legal Deadline: None.

Abstract: The Environmental Protection Agency (EPA) published the final Lead and Copper Rule Revision (LCRR) on January 15, 2021. EPA is currently considering revising this rulemaking. This action is consistent with presidential directives issued on January 20, 2021, to the heads of Federal agencies to review certain regulations, including the LCRR (E.O. 13990). EPA will complete its review of the rule in accordance with those directives and conduct important consultations with affected parties. This review of the LCRR will be consistent with the policy aims set forth in Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities through the Federal Government.

Statement of Need: The EPA promulgated the final Lead and Copper Rule Revision (LCRR) on January 15, 2021 (86 FR 4198). Consistent with the directives of Executive Order 13990, the EPA is currently considering revising this rulemaking. The EPA will complete its review of the rule in accordance with those directives and conduct important consultations with affected parties. The EPA understands that the benefits of clean water are not shared equally by all communities and this review of the LCRR will be consistent with the policy aims set forth in Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities through the Federal Government.”

Summary of Legal Basis: The Safe Drinking Water Act, section 1412, National Primary Drinking Water Regulations, authorizes EPA to initiate the development of a rulemaking if the agency has determined that the action maintains or improves the public health.

Alternatives: To Be Determined.

Anticipated Cost and Benefits: To Be Determined.

Risks: To Be Determined.

Timetable:
Perfluorooctanesulfonic Acid (PFOS) and Perfluorooctanoic Acid (PFOA) and Substances (PFAS): Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) National Primary Drinking Water Regulation Rulemaking

**Priority:** Other Significant. Major status under 5 U.S.C. 801 is undetermined.

**Unfunded Mandates:** Undetermined.

**Legal Authority:** 42 U.S.C. 300f et seq.

**Safe Drinking Water Act**

**CFR Citation:** 40 CFR 141; 40 CFR 142.


**Abstract:** On March 3, 2021, the Environmental Protection Agency (EPA) published the Fourth Regulatory Determinations in Federal Register, including a determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) in drinking water. Per the Safe Drinking Water Act, following publication of the Regulatory Determination, the Administrator shall propose a maximum contaminant level goal (MCLG) and a national primary drinking water regulation (NPDWR) not later than 24 months after determination and promulgate a NPDWR within 18 months after proposal. With this action, EPA intends to develop a proposed national primary drinking water regulation for PFOA and PFOS, and as appropriate, take final action. Additionally, EPA will continue to consider other PFAS as part of this action.

**Statement of Need:** EPA has determined that PFOA and PFOS may have adverse health effects; that PFOA and PFOS occur in public water systems with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by public water systems.

**Summary of Legal Basis:** The EPA is developing a PFAS NPDWR under the authority of the Safe Drinking Water Act (SDWA), including sections 1412, 1413, 1414, 1417, 1445, and 1450 of the SDWA. Section 1412(b)(1)(A) of the SDWA requires that EPA shall publish a maximum contaminant level goal and promulgate a NPDWR if the Administrator determines that (1) the contaminant may have an adverse effect on the health of persons, (2) is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at a level of public health concern, and (3) in the sole judgment of the Administrator there is a meaningful opportunity for health risk reduction for persons served by public water systems. EPA published a final determination to regulate PFOA and PFOS on March 3, 2021 after considering public comment (86 FR 12272). Section 1412(b)(1)(E) of the SDWA requires that EPA publish a proposed Maximum Contaminant Level Goal and a NPDWR within 24 months of a final regulatory determination and that the Administrator promulgate a NPDWR within 18 months of proposal.

**Alternatives:** Undetermined.

**Anticipated Cost and Benefits:** Undetermined.

**Risks:** Studies indicate that exposure to PFOA and/or PFOS above certain exposure levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney), liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), and other effects (e.g., cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk. Both compounds were also associated with tumors in long-term animal studies.

**Timetable:**

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Public Buildings Service

PBS is the largest public real estate organization in the United States. As the landlord for the civilian Federal Government, PBS acquires space on behalf of the Federal Government through new construction and leasing, and acts as a manager for Federal properties across the country. PBS is responsible for over 370 million rentable square feet of workspace for Federal employees, has jurisdiction, custody, and control over more than 1,600 federally owned assets totaling over 180 million rentable square feet, and contracts for more than 7,000 leased assets totaling over 180 million rentable square feet.

Later in FY22, GSA expects to update the existing internal guidance and issue a new PBS Order following the release of an E.O. on Federal Sustainability which is likely to be issued in late October or early November.

Office of Government-Wide Policy

OGP sets Government-wide policy in the areas of personal and real property, mail, travel, relocation, transportation, information technology, regulatory information, and the use of Federal advisory committees. OGP also helps direct how all Federal supplies and services are acquired as well as GSA’s own acquisition programs. Pursuant to Executive Order 12866, “Regulatory Planning and Review” (September 30, 1993) and Executive Order 13563, “Improving Regulation and Regulatory Review” (January 18, 2011), the Regulatory Plan and Unified Agenda provides notice regarding OGP’s regulatory and deregulatory actions within the Executive Branch.

GSA prepared a list of 20 non-regulatory actions in the areas of Climate Risk Management, Resilience, and Adaptation; Environmental Justice; Greenhouse Gas (GHG) Reduction; Clean Energy; Energy Reduction; Water Reduction; Performance Contracting; Waste Reduction; Sustainable Buildings; and Electronics Stewardship & Data Centers. Detailed information on actions GSA is considering taking through December 31, 2025, to implement the Administration’s policy set by Executive Orders 13990 and Executive Order 14008 were provided in GSA’s Executive Order 13990 90-day response; GSA Climate Change Risk Management Plan and GSA 2021 Sustainability Plan. More specifics will be known on the Sustainability Plan when feedback is obtained from the Council on Environmental Quality (CEQ) and Office of Management and Budget (OMB).

OGP’s Office of Government wide Policy, Office of Asset and Transportation Management and Office of Acquisition Policy are prioritizing rulemaking focused on initiatives that:

- Tackle the climate change emergency.
- Promote the country’s economic resilience and improve the buying power of U.S. citizens.
- Support underserved communities, promoting equity in the Federal government; and,
- Support national security efforts, especially safeguarding Federal government information and information technology systems.

Office of Asset and Transportation Management

The Fall 2021 Unified Agenda consists of fourteen (14) active Office of Asset and Transportation Management (MA) agenda items, of which four (4) active actions are included in the Federal Travel Regulation (FTR) and ten (10) active actions are included in the Federal Management Regulation (FMR). The Federal Travel Regulation (FTR) enumerates the travel and relocation policy for all title 5 Executive Agency employees. The Code of Federal Regulations (CFR) is available at https://ecfr.federalregister.gov/. Each version is updated as official changes are published in the Federal Register (FR).

The FTR is the regulation contained in title 41 of the CFR, chapters 300 through 304, that implements statutory requirements and Executive branch policies for travel by Federal civilian employees and others authorized to travel at Government expense. The FTR presents policies in a clear manner to both agencies and employees to assure that official travel is performed responsibly.

The Federal Management Regulation (FMR) establishes policy for Federal aircraft management, mail management, transportation, personal property, real property, and committee management.

MA Rulemaking That Tackles Climate Change

FTR Case 2020–301–1, Definition for “Fuel”, Rental Car Policy Updates and Clarifications, replaces the word “gasoline” where appropriate and replaces it with the term “fuel” to acknowledge the use of alternative fuels, such as electricity.

FTR Case 2021–301–1, Removal of the word “gasoline” replaces the term “fuel” to acknowledge the use of alternative fuels, such as electricity.

GSA’s Office of Acquisition Policy established the Facility Security Level (FSL) of III, IV, V, and VI of Acquisition Policy—General Services Administration Acquisition Regulations (GSAR).

Office of Acquisition Policy—General Services Administration Acquisition Regulation

The GSAR establishes agency acquisition regulations that affect GSA’s business partners (e.g., prospective offerors and contractors) and acquisition of leasehold interests in real property. The latter are established under the authority of 40 U.S.C. 585. The GSAR implements contract clauses, solicitation provisions, and standard forms that control the relationship between GSA and contractors and prospective contractors.

MV Rulemaking That Promotes Economic Resilience

GSA Case 2021–G530, Extension of Federal Minimum Wage to Lease Acquisitions, will increase efficiency and cost savings in the work performed for leases with the Federal Government by increasing the hourly minimum wage paid to those contractors in accordance with Executive Order 14026. “Increasing the Minimum Wage for Federal Contractors” dated April 27,
2021, and Department of Labor regulations at 29 CFR part 23.

**MV Rulemaking That Supports Equity and Underserved Communities**

GSAR Case 2020–G511, Updated Guidance for Non-Federal Entities Access to Federal Supply Schedules, will clarify the requirements for use of Federal Supply Schedules by eligible Non-Federal Entities, such as state and local governments. The regulatory changes are intended to increase understanding of the existing guidance and expand access to GSA sources of supply by eligible Non-Federal Entities, as authorized by historic statutes including the Federal Supply Schedules Usage Act of 2010.

GSAR Case 2021–G529, Updates to References to Individuals with Disabilities, will provide more inclusive acquisition guidance for underserved communities by updating references from “handicapped individuals” to “individuals with disabilities”, pursuant to Section 508 of the Rehabilitation Act.

**Rulemaking That Supports National Security**

GSAR Case 2016–G511, Contract Requirements for GS Information Systems, will streamline and update requirements for contracts that involve GS information systems. GS’s policies on cybersecurity and other information technology requirements have been previously issued and communicated by the Office of the Chief Information Officer through the GS public website. By incorporating these requirements into the GSAR, the GSAR will provide centralized guidance to ensure consistent application across the organization.

GSAR Case 2020–G534, Extension of Certain Telecommunication Prohibitions to Lease Acquisitions, will protect national security by prohibiting procurement from certain covered entities using covered equipment and services in lease acquisitions pursuant to Section 889 of the National Defense Authorization Act for Fiscal Year 2019. The regulatory changes will implement the Section 889 requirements in lease acquisitions by requiring inclusion of the related Federal Acquisition Regulation (FAR) provisions and clauses.

GSAR Case 2021–G522, Contract Requirements for High-Security Leased Space, will incorporate contractor disclosure requirements and access limitations for high-security leased space pursuant to the Secure Federal Leases Act. Covered entities are required to identify whether the beneficial owner of a high-security leased space, including an entity involved in the financing thereof, is a foreign person or entity when first submitting a proposal and annually thereafter.

GSAR Case 2021–G527, Immediate and Highest-Level Owner for High-Security Leased Space, addresses the risks of foreign ownership of Government-leased real estate and requires the disclosure of immediate and highest-level ownership information for high-security space leased to accommodate a Federal agency.

Dated: September 8, 2021.
Name: Krystal J. Brumfield,
Associate Administrator, Office of Government-wide Policy.

**BILLING CODE 6820–34–P**

**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)**

**Statement of Regulatory Priorities**

The National Aeronautics and Space Administration’s (NASA) aim is to increase human understanding of the solar system and the universe that contains it and to improve American aeronautics ability. NASA’s basic organization consists of the Headquarters, nine field Centers, the Jet Propulsion Laboratory (a federally funded research and development center), and several component installations which report to Center Directors. Responsibility for overall planning, coordination, and control of NASA programs is vested in NASA Headquarters, located in Washington, DC.

NASA continues to implement programs according to its 2018 Strategic Plan. The Agency’s mission is to “Lead an innovative and sustainable program of exploration with commercial and international partners to enable human expansion across the solar system and bring new knowledge and opportunities back to Earth. Support growth of the Nation's economy in space and aeronautics, increase understanding of the universe and our place in it, work with industry to improve America's aerospace technologies, and advance American leadership.” The FY 2018 Strategic Plan (available at https://www.nasa.gov/sites/default/files/atoms/files/nasa_2018_strategic_plan.pdf) guides NASA’s program activities through a framework of the following four strategic goals:

- **Strategic Goal 1**: Expand human knowledge through new scientific discoveries.
- **Strategic Goal 2**: Extend human presence deeper into space and to the Moon for sustainable long-term exploration and utilization.
- **Strategic Goal 3**: Address national challenges and catalyze economic growth.
- **Strategic Goal 4**: Optimize capabilities and operations.

**NASA’s Regulatory Philosophy and Principles**

The Agency’s rulemaking program strives to be responsive, efficient, and transparent. NASA adheres to the general principles set forth in Executive Order 12866, “Regulatory Planning and Review.” NASA is a signatory to the Federal Acquisition Regulatory (FAR) Council. The FAR at 48 CFR chapter 1 contains procurement regulations that apply to NASA and other Federal agencies. Pursuant to 41 U.S.C. 1302 and FAR 1.103(b), the FAR is jointly prepared, issued, and maintained by the Secretary of Defense, the Administrator of General Services, and the Administrator of NASA, under their several statutory authorities.

NASA is also mindful of the importance of international regulatory cooperation, consistent with domestic law and U.S. trade policy, as noted in Executive Order 13609, “Promoting International Regulatory Cooperation” (May 1, 2012). NASA, along with the Departments of State, Commerce, and Defense, engage with other countries in the Wassenaar Arrangement, Nuclear Suppliers Group, Australia Group, and Missile Technology Control Regime through which the international community develops a common list of items that should be subject to export controls. NASA has also been a key participant in interagency efforts to overhaul and streamline the U.S. Munitions List and the Commerce Control List. These efforts help facilitate transfers of goods and technologies to allies and partners while helping prevent transfers to countries of national security and proliferation concerns.

**NASA Priority Regulatory Actions**

NASA is highlighting one priority in this agenda and a short summary is provided below.

**Procedures for Implementing the National Environmental Policy Act (NEPA)**

NASA is revising its policy and procedures for implementing the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality (CEQ) regulations. These proposed amendments would update procedures.
National Archives and Records Administration (NARA)

Statement of Regulatory Priorities

The National Archives and Records Administration (NARA) primarily issues regulations directed to other Federal agencies. These regulations include records management, information services, and information security. For example, records management regulations directed to Federal agencies concern the proper management and disposition of Federal records. Through the Information Security Oversight Office (ISOO), NARA also issues Government-wide regulations concerning information security classification, controlled unclassified information (CUI), and declassification programs; through the Office of Government Information Services, NARA issues Government-wide regulations concerning Freedom of Information Act (FOIA) dispute resolution services and FOIA ombudsman functions; and through the Office of the Federal Register, NARA issues regulations concerning publishing Federal documents in the Federal Register, Code of Federal Regulations, and other publications.

NARA regulations directed to the public primarily address access to and use of our historically valuable holdings, including archives, donated historical materials, Nixon Presidential materials, and other Presidential records. NARA also issues regulations relating to the National Historical Publications and Records Commission (NHPRC) grant programs.

NARA’s regulatory priority for fiscal year 2022 is included in The Regulatory Plan. This priority is a multi-year project to update our entire set of records management regulations (36 CFR 1220–1239) to reflect an overall change for the Federal Government from paper to electronic records, account for updates in processes and technologies, and streamline these regulations.

Changes to 44 U.S.C. 3302 require NARA to issue standards for digital reproductions of records with an eye toward allowing agencies to then dispose of the original source records. Changes to 44 U.S.C. 2004 require NARA to promulgate regulations requiring all Federal agencies to transfer records to the National Archives of the United States in digital or electronic form to the greatest extent possible. In addition, our Strategic Plan for 2018–2022 establishes that we will no longer accept paper records from agencies by the end of 2022.

As a result of these deadlines, agencies have begun major digitization projects and will be doing more in the future so that they can meet deadlines and requirements for electronic records and reduce the storage and cost burdens involved with managing paper records. Under the statutory provisions in 44 U.S.C. 3302, however, agencies may not dispose of original source records due to having digitized them (prior to the disposal authority date established in a records schedule), unless they have digitized the records according to standards established by NARA. So, the first priority for our overarching records management project was to initiate two rulemaking actions in FY 2019 and FY 2020 to establish digitizing standards for Federal records. Both actions add new subparts to 36 CFR 1236, Electronic Records Management. The first regulatory action focused on digitizing temporary records (records of short-term, temporary value that are not appropriate for preservation in the National Archives of the United States) and was issued as a final rule effective on May 10, 2019. We began developing the second action during FY 2019 as well, focused on digitizing permanent records (permanently valuable and appropriate for preservation in the National Archives of the United States), and we expect to publish it as a final rule in the winter of 2021, depending upon the scope and range of agency comments.

We are also revising 36 CFR 1224, Records Disposition Programs, and 36 CFR 1225, Scheduling Records, during FY 2022 to incorporate more regular review and assessment of records. These changes include a requirement for agencies to periodically review established records schedules to ensure they remain viable and up to date. This will help agencies as they manage records and set priorities for digitizing projects.

We are also revising 36 CFR 1222, Creation and Maintenance of Federal Records, to incorporate requirements in the Electronic Messages Preservation Act (EMPA), passed in January 2021. Although our regulations at 36 CFR 1236 already include requirements for preserving electronic messages that are records, these requirements are general requirements for all electronic records, so we are also adding them to 36 CFR 1222 to comply with the new law.

During FY 2021 we also worked on extensive revisions to all the records management regulations, which will continue during FY 2022 and FY 2023.

U.S. Office of Personnel Management

Statement of Regulatory and Deregulatory Priorities Fall 2021 Unified Agenda

- Mission and Overview
  - OPM works in several broad categories to recruit, retain and honor a world-class workforce for the American people.

- We Management job announcement postings at USAJOBS.gov, and set policy on government-wide hiring procedures.

- We up hold and defend the merit systems in Federal civil service, making sure that the Federal workforce uses fair practices in all aspects of personnel management.

- We manage pension benefits for retired Federal employees and their families. We also administer health and other insurance programs for Federal employees and retirees.

- We provide training and development programs and other management tools for Federal employees and agencies.

- In many cases, we take the lead in developing, testing and implementing new government-wide policies that relate to personnel issues.

- OPM is required to amend the regulations to implement statutory and policy initiatives. OPM prioritization is focused on initiatives that:
  - Actions that advance equity and support underserved, vulnerable and marginalized communities;
  - Actions that promote fair and ethical treatment of Federal employees;
  - Actions that advance equity and support underserved, vulnerable and marginalized communities;
  - Actions that ensure the Federal workforce is a model employer for the 21st century.

Statement of Regulatory and Deregulatory Priorities Management Priorities

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The Office of Personnel Management (OPM) is issuing proposed regulations governing implementation of the Elijah E. Cummings Federal Employee Discrimination Act of 2020, which became law on January 1, 2021. OPM is proposing to conform its regulations to the Act, which amends existing or adds new requirements to the Notification and Federal Employee Anti-Discrimination and Retaliation Act of 2002. The proposed regulations, among other things, establish a new requirement to post findings of discrimination that have been made, establish new electronic format reporting requirements for Agencies, and establish new disciplinary action reporting requirements for Agencies.

- **The Fair Chance Act**

3206–AO00

The Fair Chance Act prohibits agencies from making inquiries or soliciting information concerning job applicant’s criminal history record information prior to receipt of conditional offer. It requires OPM to publish regulations by December 20, 2020, covering the entire Executive civil service. Regulations must include position specific exceptions and a process for receiving and investigating complaints against Federal employees by applicants and specifies adverse actions for founded violations.


3206–AO26

The Office of Personnel Management (OPM) is issuing proposed regulations governing implementation of the Elijah E. Cummings Federal Employee Discrimination Act of 2020, which became law on January 1, 2021. OPM is proposing to conform its regulations to the Act, which amends existing or adds new requirements to the Notification and Federal Employee Anti-Discrimination and Retaliation Act of 2002. The proposed regulations, among other things, establish a new requirement to post findings of discrimination that have been made, establish new electronic format reporting requirements for Agencies, and establish new disciplinary action reporting requirements for Agencies.

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3206–AO30

This interim final rule with comment would implement certain protections against surprise medical bills under the No Surprises Act.

- **Requirements Related to Surprise Billing: Part I**

3206–AO29

This joint interim final rule with comment with the Departments of Health and Human Services, Labor, and Treasury would implement additional protections against surprise medical bills under the No Surprises Act, including provisions related to the independent dispute resolution processes.

- **FEDVIP: Extension of Eligibility to Certain Employees on Temporary Appointments and Certain Employees on Seasonal and Intermittent Schedules; Enrollment Clarifications and Qualifying Life Events**

3206–AN01

The U.S. Office of Personnel Management (OPM) is issuing a proposed rule to expand eligibility for enrollment in the Federal Employees Dental and Vision Insurance Program (FEDVIP) to additional categories of Federal employees. This proposed rule expands eligibility for FEDVIP to certain Federal employees on temporary appointments and certain employees on seasonal and intermittent schedules that became eligible for Federal Employees Health Benefits (FEHB) enrollment beginning in 2015. This rule also expands access to FEDVIP benefits to certain firefighters on temporary appointments and intermittent emergency response personnel who became eligible for FEHB coverage in 2012. These additions will align FEDVIP with FEHB Program eligibility requirements. This proposed rule also updates the provisions on enrollment for active duty service members who become eligible for FEDVIP as uniformed service retirees pursuant to the National Defense Authorization Act of 2017 (FY17 NDAA), Public Law 108–496. In addition, this rule proposes to add qualifying life events (QLEs) for enrollees who may become eligible for enrollment in dental and/or vision services from the Department of Veterans Affairs, since this issue may impact TRICARE-eligible individuals (TEIs) and other enrollees.

- **Rulemaking That Creates and Sustains Good Jobs With a Free and Fair Choice To Join a Union and Promote Economic Resilience in General**

3206–AO23

The Office of Personnel Management (OPM) is issuing regulations governing probation on initial appointment to a competitive position, performance-based reduction in grade and removal actions and adverse actions. The rule rescinds certain regulatory changes made in an OPM final rule published at 85 FR 65940 on November 16, 2020 per E.O. 14003 on Protecting the Federal Workforce. This rule also proposes new requirements for procedural and appeal rights for dual status National Guard technicians for certain adverse actions. Elements of the November 16, 2020, rule due to statutory changes will remain in effect, such as procedures for disciplinary action against supervisors who retaliate against whistleblowers and the inclusion of appeals rights information in proposal notices for adverse actions.

- **Hiring Authority for College Graduates**

3206–AO23

The U.S. Office of Personnel Management (OPM) is issuing an interim rule to amend its career and career-conditional employment regulations. The revision is necessary to implement section 1108 of Public Law 115–232, John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019, which requires OPM to issue regulations establishing hiring authorities for certain college graduates to positions in the competitive service under 5 U.S.C. 3115. The intended effect of the authority is to provide additional flexibility in recruiting and hiring eligible and qualified individuals from all segments of society. This authority may also be a useful tool in helping agencies implement Agency Diversity, Equity, Inclusion, and Accessibility Strategic Plans as required by E.O. 14035.

- **Pathways Programs**

3206–AO25

The U.S. Office of Personnel Management (OPM) is issuing proposed regulations to modify the Pathways Internship program (IP) to allow agencies greater flexibility when making appointments. OPM is proposing these changes to improve and enhance the effectiveness of the IP consistent with E.O. 13562, which requires OPM to support agency internship needs, and E.O 14035, which requires OPM to support and promote agency use of paid internships.

**BILLING CODE 3280–F5–P**

**PENSION BENEFIT GUARANTY CORPORATION (PBGC)**

**Statement of Regulatory and Deregulatory Priorities**

The Pension Benefit Guaranty Corporation (PBGC or Corporation) is a federal corporation created under title IV of the Employee Retirement Income Security Act of 1974 (ERISA) to guarantee the payment of pension benefits earned by over 33 million workers and retirees in private-sector defined benefit plans. PBGC administers two insurance programs—one for single-employer defined benefit pension plans and a second for multiemployer defined benefit pension plans.

- **Single-Employer Program.** Under the single-employer program, when a plan terminates with insufficient assets to cover all plan benefits (distress and involuntary terminations), PBGC pays plan benefits that are guaranteed under title IX. PBGC also pays nonguaranteed plan benefits to the extent funded by plan assets or recoveries from

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employers. In fiscal year (FY) 2021, PBGC paid over $6.4 billion in benefits to nearly 970,000 retirees. Operations under the single-employer program are financed by insurance premiums, investment income, assets from pension plans trusted by PBGC, and recoveries from the companies formerly responsible for the trusted plans.

- **Multiemployer Program.** The multiemployer program covers collectively bargained plans involving more than one unrelated employer. PBGC provides financial assistance (technically in the form of a loan, though almost never repaid) to the plan if the plan is insolvent and thus unable to pay benefits at the guaranteed level. The guarantee is structured differently from, and is generally significantly lower than, the single-employer guarantee. In FY 2021, PBGC paid $230 million in financial assistance to 109 multiemployer plans. Operations under the multiemployer program generally are financed by insurance premiums and investment income. In addition, the American Rescue Plan Act of 2021 (ARP) added section 4262 of ERISA, which requires PBGC to provide special financial assistance (SFA) to certain financially troubled multiemployer plans upon application for assistance, which is funded by general tax revenues.

While risks remain, the financial status of the single-employer program improved to a positive net financial position of $30.9 billion at the end of FY 2021. Due to enactment of ARP, the net financial position of the multiemployer program improved dramatically during FY 2021 from a negative net position of $63.7 billion at the end of FY 2020 to a positive net position of $481 million at the end of FY 2021. ARP substantially improves the financial condition and the outlook for PBGC’s multiemployer program. By forestalling the near-term insolvency of the most troubled multiemployer plans, the multiemployer program is no longer expected to go insolvent in FY 2026 and can accumulate a greater level of reserve assets in its insurance fund in the near-term.

To carry out its statutory functions, PBGC issues regulations on such matters as how to pay premiums, when reports are due, what benefits are covered by the insurance program, how to terminate a plan, the liability for underfunding, and how withdrawal liability works for multiemployer plans. PBGC follows a regulatory approach that seeks to encourage the continuation and maintenance of securely-funded defined benefit plans. In developing new regulations and reviewing existing regulations, PBGC seeks to reduce burdens on plans, employers, and participants, and to ease and simplify employer compliance wherever possible. PBGC particularly strives to meet the needs of small businesses that sponsor defined benefit plans. In all such efforts, PBGC’s mission is to protect the retirement incomes of plan participants.

### Regulatory/Deregulatory Objectives and Priorities

PBGC’s regulatory/deregulatory objectives and priorities are developed in the context of the Corporation’s statutory purposes, priorities, and strategic goals.

Pension plans and the statutory framework in which they are maintained and terminated are complex. Despite this complexity, PBGC is committed to issuing simple, understandable, flexible, and timely regulations to help affected parties. PBGC’s regulatory/deregulatory objectives and priorities are:

- To enhance the retirement security of workers and retirees;
- To implement regulatory actions that ease compliance burdens and achieve maximum net benefits while protecting retirement security; and
- To simplify existing regulations and reduce burden.

PBGC endeavors in all its regulatory and deregulatory actions to promote clarity and reduce burden with the goal that net cost impact on the public is zero or less overall.

### American Rescue Plan

The American Rescue Plan Act of 2021 (ARP) added a new section 4262 of ERISA to create a program to enhance retirement security for more than 3 million Americans by providing special financial assistance (SFA) to certain financially troubled multiemployer plans. In turn, the SFA program improves the financial condition of PBGC’s multiemployer insurance program. For plans that adopted a benefit suspension under the Multiemployer Pension Reform Act of 2014 (MPRA), and for certain insolvent plans that suspended benefits upon insolvency, the SFA includes make-up payments of suspended benefits for participants and beneficiaries who are in pay status at the time SFA is paid, and prospective reinstatement of suspended benefits for all participants and beneficiaries.

Under new section 4262 of ERISA, PBGC was required within 120 days to issue regulations or other guidance the requirements for SFA applications. To implement the program, on July 9, 2021, PBGC released an interim final rule adding a new part 4262 to its regulations, “Special Financial Assistance by PBGC,” which was published in the Federal Register on July 12, 2021. Part 4262 provides guidance to multiemployer pension plan sponsors on eligibility, determining the amount of SFA, content of an application for SFA, the process of applying, PBGC’s review of applications, and restrictions and conditions on plans that receive SFA. PBGC also released instructions and guidance on assumptions used for determining eligibility and the amount of SFA. PBGC held two webinars related to the interim final rule on the SFA application and review process; restrictions, conditions, and reporting; agency guidance; and program resources. The public comment period on the interim final rule ended on August 12, 2021, and PBGC expects to publish a final rule in January 2022.

### Multiemployer Plans

In other multiemployer plan rulemakings, PBGC plans to publish a proposed rule prescribing actuarial assumptions which may be used by a multiemployer plan actuary in determining an employer’s withdrawal liability (RIN 1212–AB54). Section 4213(a) of ERISA permits PBGC to prescribe by regulation such assumptions.

PBGC also plans to propose a rulemaking that would add a new part 4022A to PBGC’s regulations to provide guidance on determining the monthly amount of multiemployer plan benefits guaranteed by PBGC (“Multiemployer Plan Guaranteed Benefits,” RIN 1212–AB37). For example, the proposed rule would explain what multiemployer plan benefits are eligible for PBGC’s guarantee, how to determine credited service, how to determine a benefit’s accrual rate, and how to calculate the guaranteed monthly benefit amount.

### Rethinking Existing Regulations

Most of PBGC’s regulatory/deregulatory actions are the result of its ongoing retrospective review to identify and correct unintended effects, inconsistencies, inaccuracies, and requirements made irrelevant over time. For example, PBGC’s regulatory review identified a need to improve PBGC’s recoupment of benefit overpayment rules (“Improvements to Rules on Recoupment of Benefit Overpayments,” RIN 1212–AB47). The “Benefit Payments” rulemaking (RIN 1212–AB37) would make clarifications and codify policies in PBGC’s benefit payments and valuation regulations.
involving payment of lump sums, changes to benefit form, partial benefit distributions, and valuation of plan assets. Other rulemakings would modernize PBGC’s regulations and policies by adopting up-to-date assumptions and methods that are more consistent with best practices within the pension community. For example, PBGC is considering modernizing the interest, mortality, and expense load assumptions used to determine the present value of benefits under the asset allocation regulation (for single-employer plans) and for determining mass withdrawal liability payments (for multipurpose plans) (RIN 1212–AA53).

Small Businesses
PBGC considers very seriously the impact of its regulations and policies on small entities. PBGC attempts to minimize administrative burdens on plans and participants, improve transparency, simplify filing, and assist plans to comply with applicable requirements. PBGC particularly strives to meet the needs of small businesses that sponsor defined benefit plans. In all such efforts, PBGC’s mission is to protect the retirement incomes of plan participants.

Open Government and Increased Public Participation
PBGC encourages public participation in the regulatory process. For example, PBGC’s “Federal Register Notices Open for Comment” web page highlights when there are opportunities to comment on proposed rules, information collections, and other Federal Register notices. PBGC also encourages comments on an ongoing basis as it continues to look for ways to further improve the agency’s regulations. Efforts to reduce regulatory burden in the projects discussed above are in substantial part a response to public comments.

PBGC
Final Rule Stage
170. Special Financial Assistance by PBGC

CFR Citation: 29 CFR 4262.
Legal Deadline: Other, Statutory, July 9, 2021, 120 days after date of enactment (March 11, 2021).
Section 4262(c) as added to the Employee Retirement Income Security Act of 1974 (ERISA) by section 9704 of Subtitle H of the American Rescue Plan Act of 2021, requires that within 120 days of the date of enactment of this section, PBGC shall issue regulations or guidance setting forth requirements for special financial assistance (SFA) applications under this section.

Abstract: This final rule implements section 9704 of the American Rescue Plan Act by setting forth the requirements for plan sponsors of financially troubled multiemployer defined benefit pension plans to apply for special financial assistance from the Pension Benefit Guaranty Corporation, and related requirements.

Statement of Need: This final rule is needed to implement section 9704 of the American Rescue Plan Act and set forth the requirements for plan sponsors of financially troubled multiemployer defined benefit pension plans to apply for special financial assistance from the Pension Benefit Guaranty Corporation, and related requirements.

Anticipated Cost and Benefits: In its fiscal year (FY) 2020 Projections Report, published in September 2021, PBGC estimated a range of possible outcomes for the total amount of SFA payments under the provisions of the interim final rule. PBGC used the mean value in that range—$97.2 billion—to estimate the transfer impacts of the SFA program, and estimated the average annual information collection, including application, cost of the SFA program will be about $2 million. The SFA program is expected to assist plans covering more than 3 million participants and beneficiaries, including the provision of funds to reinstate suspended benefits of participants and beneficiaries.

Timetable:

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<th>Action</th>
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<tr>
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<td>86 FR 36598</td>
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Regulatory Flexibility Analysis
Required: No.
Government Levels Affected: None.
Agency Contact: Hilary Duke, Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, Phone: 202 229–3839, Email: duke.hilary@pbgc.gov.
RIN: 1212–AB53

BILLING CODE 7709–02–P

U.S. SMALL BUSINESS ADMINISTRATION

Statement of Regulatory Priorities

Overview
The mission of the U.S. Small Business Administration (SBA) is to maintain and strengthen the Nation’s economy by enabling the establishment and viability of small businesses, and by assisting in the physical and economic recovery of communities after disasters. In accomplishing this mission, SBA strives to improve the economic environment for small businesses, including: those in rural areas, in areas that have significantly higher unemployment and lower income levels than the Nation’s averages, and those in traditionally underserved markets.

SBA has several financial, procurement, and technical assistance programs that provide a crucial foundation for those starting or growing a small business. For example, the Agency serves as a guarantor of loans made to small businesses by lenders that participate in SBA’s programs. The Agency also licenses small business investment companies that make equity and debt investments in qualifying small businesses using a combination of privately raised capital and SBA guaranteed leverage. SBA also funds various training and mentoring programs to help small businesses, particularly businesses owned by women, veterans, minorities, and other historically underrepresented groups, gain access to Federal government contracting opportunities. The Agency also provides management and technical assistance to existing or potential small business owners through various grants, cooperative agreements, or contracts. Finally, as a vital part of its purpose, SBA also provides direct financial assistance to homeowners, renters, and businesses to repair or replace their property in the aftermath of a disaster.

Reducing Burden on Small Businesses

SBA’s regulatory policy reflects a commitment to developing regulations that reduce or eliminate the burden on the public, in particular the Agency’s core constituents—small businesses. SBA’s regulatory process generally includes an assessment of the costs and benefits of the regulations as required by Executive Order No. 12866, 1993, “Regulatory Planning and Review”; Executive Order No. 13563, 2011, “Improving Regulation and Regulatory Review”; and the Regulatory Flexibility Act. SBA’s program offices are particularly invested in finding ways to
reduce the burden imposed by the Agency’s core activities in its loan, grant, innovation, and procurement programs.

**Openness and Transparency**

SBA promotes transparency, collaboration, and public participation in its rulemaking process. To that end, SBA routinely solicits comments on its regulations, even those that are not subject to the public notice and comment requirement under the Administrative Procedure Act. Where appropriate, SBA also conducts hearings, webinars, and other public events as part of its regulatory process.

**Regulatory Framework**

The SBA Strategic Plan serves as the foundation for the regulations that the Agency will develop during the next twelve months. This Strategic Plan provides a framework for strengthening, streamlining, and simplifying SBA’s programs; and leverages collaborative relationships with other agencies and the private sector to maximize the tools small business owners and entrepreneurs need to drive American innovation and strengthen the economy.

The plan sets out four Strategic Goals:
1. Support small business revenue and job growth;
2. Build healthy entrepreneurial ecosystems and create business friendly environments;
3. Restore small businesses and communities after disasters; and
4. Strengthen SBA’s ability to serve small businesses.

The regulations reported in SBA’s semi-annual Regulatory Agenda and Plan are intended to facilitate achievement of these goals and objectives.

Over the past 18 months, SBA’s regulatory activities focused primarily on rulemakings that were necessary to implement the Paycheck Protection Program and the Economic Injury Disaster Loan program, which made it possible for millions of businesses, sole proprietors, independent contractors, certain non-profits, and veterans’ organizations, among other entities, to receive financial assistance to alleviate the economic crisis caused by the COVID–19 pandemic. Over the next 12 months, SBA will take further regulatory action if necessary to tweak requirements for the programs to further advance the country’s economic recovery.

**Administration’s Priorities**

To the extent possible and consistent with the Agency’s statutory purpose, SBA will also take steps to support the Administration’s priorities highlighted in Fall 2021 Data Call for the Unified Agenda of Federal Regulatory and Deregulatory Action (08/16/2021), namely: (1) Actions that advance the country’s economic recovery and continue to address any additional necessary COVID-related issues; (2) actions that tackle the climate change emergency; (3) actions that advance equity and support underserved, vulnerable and marginalized communities; and (4) actions that create and sustain good jobs with a free and fair choice to join a union and promote economic resiliency in general.

**Advancing the Country’s Economic Recovery and Addressing Additional COVID-Related Issues**

As small businesses across multiple industries continue to face economic uncertainties, SBA will continue to provide financial assistance consistent with existing statutory authorities to help alleviate the financial burdens still facing small businesses. SBA will take steps, including regulatory action where necessary, to modify requirements for its various COVID-related assistance programs to alleviate burdens on eligible program recipients and further advance the country’s economic recovery.

**Tackling the Climate Change Emergency and Promoting Economic Resilience**

To help combat the climate change crisis, SBA is implementing a multi-year priority goal to help prepare and rebuild resilient communities by enhancing communication efforts for mitigation.

SBA’s regulations in 13 CFR part 123 contain the legal framework for financing projects specifically targeted for pre-disaster and post-disaster mitigation projects. Proceeds from other SBA financing programs can also be used for mitigating measures. At this point no regulations are necessary to implement any of these options; therefore, SBA will focus its efforts on educating the public on the benefits of investing in mitigation and resilience projects and also on increasing awareness of SBA loan programs that can be used for renovating, retrofitting, or purchasing buildings and equipment to reduce greenhouse gas emissions; improving energy efficiency; or enabling the development of innovative solutions that support the green economy.

**Regulatory Plan Rule**

In the context of its Regulatory Agenda, SBA plans to prioritize the regulations that are necessary to implement new authority for SBA to take over responsibility from the Department of Veterans Affairs (VA) for certifying veteran-owned small businesses (VOSBs) and service-disabled veteran-owned small businesses (SDVOSBs) for sole source and set-asides contracts. Section 862 of the NDAA FY 2021 requires transfer of the program to SBA on January 1, 2023. SBA is prioritizing development of the required rulemaking to ensure that the affected public is aware of the regulatory requirements that will govern the VOSB and SDVOSB certification process at SBA and that the Agency is positioned to begin certifications on the transfer date. This statutorily mandated process is critical since the Agency’s ongoing efforts to support businesses in underserved markets, including veteran-
owned small businesses. And as businesses struggle to overcome the financial effects of the COVID pandemic, promulgating the rule before the transfer date will also ensure there is no gap in the certification process. Any delay in certification could adversely impact those VOSBs and SDVOSBs seeking access to the billions of dollars in federal government procurement opportunities and could impact their economic recovery.

Title: Service-Disabled Veteran-Owned Small Business Certification (RIN 3245–AH69)

The Veteran-Owned Small Business (VOSB) and Service-Disabled Veteran-Owned Small Business (SDVOSB) Programs, as managed by the Department of Veterans Affairs (VA) in compliance with 38 U.S.C. 8127, authorize Federal contracting officers to restrict competition to eligible VOSBs and SDVOSBs for VA contracts. There is currently no government wide VOSB set-aside program, and firms seeking to be awarded SDVOSB set-aside contracts with Federal agencies other than the VA are required only to self-certify their SDVOSB status. Section 862 of the National Defense Authorization Act, Fiscal Year 2021, Public Law 116–283, 128 Stat. 3292 (January 1, 2021), amended the VA certification authority and transferred the responsibility for certification of VOSBs and SDVOSBs to SBA and created a government-wide certification program for Veteran-owned Small Businesses (VOSBs) and Service-Disabled Veteran-Owned Small Businesses (SDVOSBs). The certification requirement applies only to participants wishing to compete for set-aside or sole-source contracts. When the program is established (target date January 2023), SDVOSBs that are not certified will not be eligible to compete on set-asides or receive sole-source contracts in the SDVOSB Program. NDAA also created a one-year grace period for SDVOSBs firms currently self-certified to apply to SBA for certification.

Statement of Need: Section 862 requires the Administrator to establish procedures necessary to implement the amendments. The Advanced Notice of Proposed Rulemaking (ANPRM) is intended to gather feedback from the public, particularly those VOSBs and SDVOSBs that would seek certification from SBA on how to implement the transferred authority and establish a government-wide certification program for SDVOSBs. In addition to the statutory requirement to establish regulations and procedures to implement the NDAA 2021 amendments, SBA’s current regulations are also in conflict with said changes. Therefore, revised regulations are necessary not only to incorporate the new authority, but also to amend any inconsistencies.

Anticipated Cost and Benefits: SBA’s SDVOSB/VOSB certification program ensures that only eligible small businesses receive set-aside contracts from agencies throughout the federal government. Since agencies cannot award to small businesses unless they are certified by SBA, this regulation may reduce an agency’s time and costs associated with contract award, protest, and appeal. The statutory requirement for SBA to establish a government-wide certification program for SDVOSBs and certify VOSBs and SDVOSBs imposes a significant program cost burden for the agency that is currently unfunded. There are no financial costs to the applicant other than the time spent preparing and submitting the application.

Risks: There is a risk that SBA’s certification program would fail to identify an ineligible entity that would subsequently receive a set-aside contract. This risk is reduced by existing SDVOSB/VOSB protest procedures and periodic eligibility examinations of participant firms.

Timetable:

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Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Edmund Bender, Small Business Administration, 409 3rd Street SW, Washington, DC 20416, Phone: 202 205–0455.

RIN: 3245–AH69

BILLING CODE 8026–03–P

SOCIAL SECURITY ADMINISTRATION (SSA)

I. Statement of Regulatory Priorities

We administer the Retirement, Survivors, and Disability Insurance programs under title II of the Social Security Act (Act), the Supplemental Security Income (SSI) program under title XVI of the Act, and the Special Veterans Benefits program under title VIII of the Act. As directed by Congress, we also assist in administering portions of the Medicare program under title XVIII of the Act. Our regulations codify the requirements for eligibility and entitlement to benefits and our procedures for administering these
programs. Generally, our regulations do not impose burdens on the private sector or on State or local governments, except for the States’ Disability Determination Services and representatives of claimants. However, our regulations can impose burdens on the private sector in the course of evaluating a claimant’s initial or continued eligibility. We fully fund the Disability Determination Services in advance or via reimbursement for necessary costs in making disability determinations. The entries in our regulatory plan represent issues of major importance to the Agency. Through our regulatory plan, we intend to:

A. Simplify a specific policy within the SSI program by no longer considering food expenses as a source of In-Kind Support and Maintenance (RIN 0960–AI60);

B. Revise our regulations to confirm that we will allow a $20 tolerance that prevents us from assessing In-Kind Support and Maintenance if an SSI claimant is close to meeting his or her fair share of expenses (RIN 0960–AI68); and

C. Simplify policies and business processes while assisting vulnerable populations who may need assistance providing their intent to file and recording their protective filing. We would also allow third parties who are assisting the potential claimants to submit a written statement regardless of whether the written inquiry is signed, which will protect claimants who are unable to provide the information by themselves (RIN 0960–AI69).

II. Regulations in the Proposed Rule Stage

Two of our regulations target changes to the In-Kind Support and Maintenance policy in our SSI program. They would simplify a specific policy within the SSI program by no longer considering food expenses as a source of In-Kind Support and Maintenance (RIN 0960–AI60) and would revise our regulations to confirm that we will allow a $20 tolerance that prevents us from assessing In-Kind Support and Maintenance if an SSI claimant is close to meeting his or her fair share of expenses (RIN 0960–AI68).

In addition, our proposed regulations would simplify policies and business processes while assisting vulnerable populations who may need assistance providing their intent to file and recording their protective filing. The proposed regulation would allow third parties who are assisting the potential claimants to submit a written statement regardless of whether the written inquiry is signed, which will protect claimants who are unable to provide the information by themselves (RIN 0960–AI69).

III. Regulations in the Final Rule Stage

We are not including any of our regulations in the final rule stage in this statement of regulatory priorities.

Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563, “Improving Regulation and Regulatory Review” (January 18, 2011), SSA regularly engages in retrospective review and analysis for multiple existing regulatory initiatives. These initiatives may be proposed or completed actions, and they do not necessarily appear in The Regulatory Plan. You can find more information on these completed rulemakings in past publications of the Unified Agenda at www.reginfo.gov in the “Completed Actions” section for the Social Security Administration.

SSA

Proposed Rule Stage

172. Omitting Food From In-Kind Support and Maintenance Calculations


CFR Citation: 20 CFR 416.1102; 20 CFR 416.1130; 20 CFR 416.1131.

Legal Deadline: None.

Abstract: We propose to change the definition of In-Kind Support and Maintenance (ISM) to no longer consider food expenses as a source of ISM. Instead, ISM would only be derived from shelter expenses (i.e., costs associated with room, rent, mortgage payments, real property taxes, heating fuel, gas, electricity, water, sewerage, and garbage collection services). The present definition of ISM is used across several regulations and this regulatory change would necessitate minor changes to other related regulations.

Statement of Need: This change would remove food cost when we determine ISM. By doing so, it streamlines the ISM policy and resulting SSI program complexity.

Anticipated Cost and Benefits: To be provided with publication of the proposed rule.

Timetable:

NPRM ................. 04/00/22

Regulatory Flexibility Analysis Required: No.

Small Entities Affected: No.

Government Levels Affected: None.

Agency Contact: Scott Logan, Social Security Insurance Specialist, Social Security Administration, Office of Income Security Programs, 6401 Security Boulevard, Baltimore, MD 21235–6401, Phone: 410 966–5927, Email: scott.logan@ssa.gov.

RIN: 0960–AI60

SSA

173. • $20 Tolerance Rule To Establish That the Individual Meets the Pro-Rata Share of Household Expenses When Living in the Household of Another

Priority: Other Significant.


CFR Citation: 20 CFR 416.1133.

Legal Deadline: None.

Abstract: When SSI claimants live in another person’s household, their benefits may be reduced because they could receive in-kind support and maintenance from that household. However, their benefits will not be reduced if they demonstrate that they are paying their pro-rata share of the household’s expenses. If SSI claimants do not contribute their pro-rata share of household expenses, but they do contribute an amount that is within $20 of their share of household expenses, we treat the situation as if the claimants pay their pro-rata share under our tolerance policy. In this situation, we would not reduce a claimant’s benefit because of in-kind support and maintenance. This proposed rule seeks to codify this policy.

Statement of Need: This change would reinforce a tolerance that prevents SSA from assessing ISM if a claimant is within a specific dollar amount of meeting their fair share when living in the home on another.

Anticipated Cost and Benefits: This is a new draft regulation proposal and we have not completed the regulation specifications. We are unable to formally project costs and benefits.

Timetable:

NPRM ................. 05/00/22
SSA

174. Inquiry About SSI Eligibility at Application Filing Date Which Will Remove the Requirement for a Signed Written Statement and Will Expand Protective Filing

Priority: Other Significant.
Legal Authority: 42 U.S.C. 902 (a)(5)
CFR Citation: 20 CFR 416.340; 20 CFR 416.345.
Legal Deadline: None.
Abstract: Under current regulations, a protective filing may be established only if the claimant, the claimant’s spouse, or a person who may sign an application on the claimant’s behalf (20 CFR 416.340(b), 416.345(b)) submits a signed written statement expressing intent to file, or makes an oral inquiry. Under our regulations, people who may sign such an application include parents or caregivers of claimants who are minor children or mentally incompetent (20 CFR 416.315). However, the regulations do not authorize other third parties to sign an application or otherwise establish a protective filing date, unless the situation meets the regulatory exception. The exception only allows considering a protective filing from a third party if it prevents a loss of benefits due to a delay in filing when there is a good reason why the claimant cannot sign an application.

Revising the regulations and combining them to provide one set of rules for both situations will simplify policies and business processes while assisting vulnerable populations who may need assistance providing their intent to file and recording their protective filing. Amending both regulations to allow third parties who are assisting the potential claimants to submit a written statement regardless of whether the written inquiry is signed will protect claimants who are unable to provide the information by themselves.

Anticipated Cost and Benefits: We cannot quantify costs and benefits at this time, but this change would allow SSA technicians to schedule appointments from the information submitted by the third party without first having to contact the potential claimant to confirm their intent to file nor developing for a good reason why the third party is providing us with the claimant’s intent to file. We see benefits here in terms of work hours for SSA employees and in terms of protective filings established for vulnerable populations requiring assistance.

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FEDERAL ACQUISITION REGULATION (FAR)
The Federal Acquisition Regulation (FAR) was established to codify uniform policies for acquisition of supplies and services by executive agencies. It is issued and maintained jointly under the statutory authorities granted to the Secretary of Defense, Administrator of General Services, and the Administrator, National Aeronautics and Space Administration, known as the Federal Acquisition Regulatory Council (FAR Council). Overall statutory authority is found at chapters 11 and 13 of title 41 of the United States Code.

Pursuant to Executive Order 12866, “Regulatory Planning and Review” (September 30, 1993) and Executive Order 13563, “Improving Regulation and Regulatory Review” (January 18, 2011), the Regulatory Plan and Unified Agenda provide notice about the FAR Council’s proposed regulatory and deregulatory actions within the Executive Branch. The Fall 2021 Unified Agenda consists of forty-seven (48) active agenda items.

Rulemaking Priorities
The FAR Council is required to amend the Federal Acquisition Regulation to implement statutory and policy initiatives. The FAR Council prioritization is focused on initiatives that:

- Promote the country’s economic resilience, including addressing COVID-related issues.
- Tackle the climate change emergency.
- Support equity and underserved communities; and
- Support national security efforts, especially safeguarding Federal Government information and information technology systems.

Rulemaking That Promotes Economic Resilience

FAR Case 2021–014, “Increasing the Minimum Wage for Contractors,” will increase efficiency and cost savings in the work performed by parties who contract with the Federal Government by increasing the hourly minimum wage paid to those contractors in accordance with Executive Order 14026, “Increasing the Minimum Wage for Federal Contractors” dated April 27, 2021, and Department of Labor regulations at 29 CFR part 23.

FAR Case 2021–008, Amendments to the FAR Buy American Act Requirements, will strengthen the impact of the Buy American Act through amendments, such as increasing the domestic content threshold and enhancing price preference for critical domestic products, in accordance with section 8 of Executive Order 14005, “Ensuring the...
Future is Made in All of America by All of America’s Workers.”

Rulemaking That Tackles Climate Change


FAR Case 2021–016, “Minimizing the Risk of Climate Change in Federal Acquisitions,” will consider amendments to ensure major agency procurements minimize the risk of climate change and require consideration of the social cost of greenhouse gas emissions in procurement decisions per section 5(b)(ii) of Executive Order 14030, “Climate-Related Financial Risk.”

Rulemaking That Supports Equity andUnderserved Communities

FAR Case 2021–010, “Subcontracting to Puerto Rican and Other Small Businesses,” will provide contracting incentives to mentors that subcontract to firms that are Puerto Rican businesses in accordance with section 861 of the National Defense Authorization Act of Fiscal Year 2019 as implemented in the Small Business Administration final rule published October 16, 2020.

FAR Case 2021–012, 8(a) Program, will implement regulatory changes made to the 8(a) Business Development Program by the Small Business Administration, in its final rule published in the Federal Register on October 16, 2020, which provided clarifications on offer and acceptance, certificate of competency and follow-on requirements.

FAR Case 2020–013, “Certification of Women-Owned Small Businesses,” will implement the statutory requirement for certification of women-owned and economically disadvantaged women-owned small businesses participating in the Women-Owned Small Business Program, as implemented by the Small Business Administration in its final rule published May 11, 2020.

FAR Case 2019–007, “Update of Historically Underutilized Business Zone Program,” will implement SBA’s regulatory changes issued in its final rule published on November 26, 2019. The regulatory changes are intended to reduce the regulatory burden associated with the Historically Underutilized Business Zone (HUBZone) Program.

Rulemakings That Support National Security

FAR Case 2021–017, “Cyber Threat and Incident Reporting and Information Sharing,” will increase the sharing of information about cyber threats and incident information and require certain contractors to report cyber incidents to the Federal Government to facilitate effective cyber incident response and remediation per sections 2(b), (c), and (g)(i) of Executive Order 14028, “Improving the Nation’s Cybersecurity.”

FAR Case 2021–019, “Standardizing Cybersecurity Requirements for Unclassified Information Systems,” will standardize cybersecurity contractual requirements across Federal agencies for unclassified information systems per sections 2(i) and 8(b) of Executive Order 14028, Improving the Nation’s Cybersecurity.

FAR Case 2020–011, “Implementation of Issued Exclusion and Removal Orders,” will implement authorities authorized by section 2020 of the SECURE Technology Act for the Federal Acquisition Security Council (FASC), the Secretary of Homeland Security, the Secretary of Defense and the Director of National Intelligence to issue exclusion and removal orders. These exclusions and removal orders are issued to protect national security by excluding certain covered products, services, or sources from the Federal supply chain.

Dated: September 8, 2021.

Name: William F. Clark, Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

BILLING CODE 6820–EP–P

CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

Statement of Regulatory Priorities

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of death and injury associated with consumer products. To achieve this goal, CPSC, among other things:

• Develops mandatory product safety standards or bans when other efforts are inadequate to address a safety hazard, or where required by statute;
• Obtains repairs, replacements, or refunds for defective products that present a substantial product hazard;
• Develops information and education campaigns about the safety of consumer products;
• Participates in the development or revision of voluntary product safety standards; and
• Follows statutory mandates.

Unless otherwise directed by congressional mandate, when deciding which of these approaches to take in any specific case, CPSC gathers and analyzes data about the nature and extent of the risk presented by the product. The Commission’s rules at 16 CFR 1009.8 require the Commission to consider the following criteria, among other factors, when deciding the level of priority for any particular project:

• The frequency and severity of injuries;
• The causality of injuries;
• Chronic illness and future injuries;
• Costs and benefits of Commission action;
• The unforeseen nature of the risk;
• The vulnerability of the population at risk;
• The probability of exposure to the hazard; and
• Additional criteria that warrant Commission attention.

Significant Regulatory Actions

Currently, the Commission is considering taking action in the next 12 months on one rule, table saws (RIN 3041–AC31), which would constitute a “significant regulatory action” under the definition of that term in Executive Order 12866.

BILLING CODE 6355–01–P

FEDERAL TRADE COMMISSION (FTC)

Statement of Regulatory Priorities

The Federal Trade Commission is an independent agency charged with rooting out unfair methods of competition and unfair or deceptive acts or practices. This mission is vital to our national interest because, when markets are fair and competitive, honest businesses and consumers alike reap the rewards. The Commission is committed to deploying all its tools to realize this mission.

I. New Circumstances Facing the Commission

In 2021, a number of changed circumstances caused the Commission to consider deploying new tools to advance its mission. First, the Supreme Court decided that the Commission cannot invoke its authority under Section 13(b) of the FTC Act to seek restitution or disgorgement in federal court. Second, the Commission, after

Continued

3 See AMG Capital Mgmt., LLC v. FTC, 141 S. Ct. 1341, 1352 (2021). The Commission has called on Congress to restore its ability to seek disgorgement and restitution. The Consumer Protection and Recovery Act, which would fix the adverse court
careful study, streamlined its own Rules of Practice, eliminating extra-bureaucratic steps and unnecessary formalities by returning to the statutory text Congress enacted in section 18 of the FTC Act, which will make new consumer-protection rulemakings more feasible and efficient while still preserving robust public participation.4

As the Supreme Court noted in its decision, consumer redress remains available for cases that involve a consumer-protection rule violation.5

Third, the case-by-case approach to promoting competition, while necessary, has proved insufficient, leaving behind a hyper-concentrated economy whose harms to American workers, consumers, and small businesses demand new approaches. Accordingly, the Commission in the coming year will consider developing both unfair-methods-of-competition rulemakings as well as rulemakings to define with specificity unfair or deceptive acts or practices.

The Commission is particularly focused on developing rules that allow the agency to recover redress for consumers who have been defrauded and seek penalties for firms that engage in data abuses. The Commission’s recent action to prohibit Made in USA labeling fraud offers a model for how the agency can deter the worst abuses without imposing burdens on honest businesses.6

Among the many pressing issues consumers confront in the modern economy, the abuses stemming from surveillance-based business models are particularly alarming. The Commission is considering whether rulemaking in this area would be effective in curbing lax security practices, limiting intrusive surveillance, and requiring that algorithmic decision-making does not result in unlawful discrimination. Importantly, it is not only consumers that are threatened by surveillance-based business models but also competition.

Over the coming year, the Commission will also explore whether rules defining certain “unfair methods of competition” prohibited by section 5 of the FTC Act would promote competition and provide greater clarity to the market. A recent Executive Order encouraged the Commission to consider competition rulemakings relating to non-compete clauses, surveillance, the right to repair, pay-for-delay pharmaceutical agreements, unfair competition in online marketplaces, occupational licensing, real-estate listing and brokerage, and industry-specific practices that substantially inhibit competition.7 The Commission will explore the benefits and costs of these and other competition rulemaking ideas.

Recently, the Commission published in the Federal Register a “Request for Public Comment Regarding Contract Terms that May Harm Fair Competition,” which included for reference two public petitions for competition rulemaking the Commission has received.8 One of those petitions was to curtail the use of non-compete clauses, and the other was to limit exclusionary contracting by dominant firms, but the Commission also solicited additional examples of unfair terms. Members of the public filed thousands of comments, which the Commission’s staff are carefully reviewing.

II. Updates on Ongoing Rulemakings

a. Periodic Regulatory Review Program

In 1992, the Commission implemented a program to review its rules and guides on a regular basis. The Commission’s review program is patterned after provisions in the Regulatory Flexibility Act, 5 U.S.C. 601–612, and complies with the Small Business Regulatory Enforcement Fairness Act of 1996. The Commission’s review program is also consistent with section 5(a) of Executive Order 12866, which directs executive branch agencies to reevaluate periodically all their significant regulations.9 Under the Commission’s program, rules and guides are reviewed on a 10-year schedule that results in more frequent reviews than are generally required by the Regulatory Flexibility Act. The public can obtain information on rules and guides under review and the Commission’s regulatory review program generally at https://www.ftc.gov/enforcement/rules/retrospective-review-ftc-rules-guides.

The program provides an ongoing, systematic approach for obtaining information about the costs and benefits of rules and guides and whether there are changes that could minimize any adverse economic effects, not just a “significant economic impact upon a substantial number of small entities.”10 As part of each review, the Commission requests public comment on, among other things, the economic impact and benefits of the rule; possible conflict between the rule and state, local, or other federal laws or regulations; and the effect on the rule of any technological, economic, or other industry changes. Reviews may lead to the revision or rescission of rules and guides to ensure that the Commission’s consumer protection and competition goals are achieved efficiently. Pursuant to this program, the Commission has rescinded 40 rules and guides promulgated under the FTC’s general authority and updated dozens of other rules and guides since the program’s inception.

(1) Newly Initiated and Upcoming Periodic Reviews of Rules and Guides

On July 2, 2021, the Commission issued an updated ten-year review schedule.11 Since the publication of the 2020 Regulatory Plan, the Commission has initiated or announced plans to initiate periodic reviews of the following rules and guides:

Business Opportunity Rule, 16 CFR 437. During the latter part of 2021, the Commission plans to initiate periodic review of the Business Opportunity Rule as part of the Commission’s systematic review of all current Commission rules and guides. The Commission plans to seek comments on, among other things, the economic impact, and benefits of this rule; possible conflict between the rule and State, local, or other Federal laws or regulations; and the effect on the rule of any technological, economic, or other industry changes. Effective in 2012, the Rule requires business-opportunity sellers to furnish prospective purchasers a disclosure document that provides information regarding the seller, the seller’s business, and the nature of the proposed business opportunity, as well as additional information to substantiate any claims about actual or potential sales, income, or profits for a prospective business-opportunity

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9 58 FR 51735 (Sept. 30, 1993).

10 5 U.S.C. 610.

11 86 FR 33239 (July 2, 2021).
purchaser. The seller must also preserve information that forms a reasonable basis for such claims.

Power Output Claims for Amplifiers Utilized in Home Entertainment Products, 16 CFR 432. On December 18, 2020, the Commission initiated periodic review of the Amplifier Rule (officially Power Output Claims for Amplifiers Utilized in Home Entertainment Products Rule). The Commission sought comments on, among other things, the economic impact, and benefits of this Rule; possible conflict between the Rule and State, local, or other Federal laws or regulations; and the effect on the Rule of any technological, economic, or other industry changes. Staff anticipates submitting a recommendation for further action to the Commission by February 2022. The Amplifier Rule establishes uniform test standards and disclosures so that consumers can make more meaningful comparisons of amplifier-performance attributes.

Hart-Scott-Rodino Antitrust Improvements Act Coverage, Exemption, and Transmittal Rules, 16 CFR 801–803. On December 1, 2020, the Commission initiated the periodic review of the Hart-Scott-Rodino Antitrust Improvements Act Coverage, Exemption, and Transmittal Rules (HSR Rules) as part of the Commission’s systematic review of all current Commission rules and guides. The comment period closed on February 1, 2021, and staff is now reviewing the comments. The HSR Rules and the Antitrust Improvements Act Notification and Report Form (HSR Form) were adopted pursuant to section 7(A) of the Clayton Act, which requires firms of a certain size contemplating mergers, acquisitions, or other transactions of a specified size to file notification with the FTC and the DOJ and to wait a designated period before consummating the transaction.

During the first quarter of 2022, staff anticipates that the Commission will propose a rulemaking to update the HSR Form and Instructions to the new cloud-based, e-filing system, which will eliminate paper filings.

Guides. During the calendar year of 2022, the Commission plans to initiate periodic review of the Guides Against Deceptive Pricing, 16 CFR 233, the Guides, 16 CFR 238, the Guide Concerning Use of the Word “Free” and Similar Representations, 16 CFR 251, and the Guides for the Use of Environmental Marketing Claims, 16 CFR 260.

(2) Ongoing Periodic Reviews of Rules and Guides

The following proceedings for the retroactive review of Commission rules and guides described in the 2020 Regulatory Plan are ongoing:

Children’s Online Privacy Protection Rule, 16 CFR 312. On July 25, 2019, the Commission issued a request for public comment on its Children’s Online Privacy Protection Rule (COPPA Rule). Although the Commission’s last COPPA Rule review ended in 2013, the Commission initiated this review early in light of changes in the marketplace. Following an extension, the public comment period closed on December 9, 2019. The FTC sought comment on all major provisions of the COPPA Rule, including its definitions, notice and parental-consent requirements, exceptions to verifiable parental consent, and safe-harbor provision. The FTC hosted a public workshop to address issues raised during the review of the COPPA Rule on October 7, 2019. Staff is analyzing and reviewing public comments.

Endorsement Guides, 16 CFR 255. On February 21, 2020, the Commission initiated a periodic review of the Endorsement Guides. The comment period, as extended, closed on June 22, 2020. FTC staff is currently reviewing the comments received. The Guides are designed to assist businesses and others in conforming their endorsement and testimonial advertising practices to the requirements of the FTC Act. Among other things, the Endorsement Guides provide that if there is a connection between the endorser and the marketer that consumers would not expect and it would affect how consumers evaluate the endorsement, that connection should be disclosed. The advertiser must also possess and rely on adequate substantiation to support claims made through endorsements in the same manner the advertiser would be required to do if it had made the representation directly.

Funeral Rule, 16 CFR 436. On March 15, 2019, the Commission initiated periodic review of the Franchise Rule (officially titled, Disclosure Requirements and Prohibitions Concerning Franchising). The comment period closed on April 21, 2019. The Commission then held a public workshop on November 10, 2020. The closing date for written comments related to the issues discussed at the workshop was December 17, 2020. The Rule is intended to give prospective purchasers of franchises the material information they need to weigh the risks and benefits of such an investment. The Rule requires franchisors to provide all potential franchisees with a disclosure document containing 23 specific items of information about the offered franchise, its officers, and other franchisees. Required disclosure topics include, for example, the franchise’s litigation history; past and current franchisees and their contact information; any exclusive territory that comes with the franchise; assistance the franchisor provides franchisees; and the cost of purchasing and starting up a franchise.

Funeral Rule, 16 CFR 453. On February 14, 2020, the Commission initiated a periodic review of the Funeral Industry Practices Rule (Funeral Rule). The comment period as extended closed on June 15, 2020. Commission staff is reviewing the comments received and anticipates submitting a recommendation for further action to the Commission by early 2022. The Rule, which became effective in 1984, requires sellers of funeral goods and services to give price lists to consumers who visit a funeral home.

Identity Theft Rules, 16 CFR 681. On May 22, 2020, the Commission initiated a periodic review of the Health Breach Notification Rule. The comment period closed on August 20, 2020. Commission staff has reviewed the comments and intends to submit a recommendation to the Commission by January 2022. The Rule requires vendors of personal health records (PHR) and PHR-related entities to provide: (1) Notice to consumers whose unsecured personally identifiable health information has been breached; and (2) notice to the Commission. Under the Rule, vendors must notify both the FTC and affected consumers whose information has been affected by a breach “without unreasonable delay and in no case later than 60 calendar days” after discovery of a data breach. Among other information, the notices must provide consumers with steps they can take to protect themselves from harm.

Identity Theft Rules, 16 CFR 681. In December 2018, the Commission initiated a periodic review of the

12 85 FR 82391 (Dec. 18, 2020).
14 84 FR 35842 (July 25, 2019).
15 84 FR 35842 (July 25, 2019).
16 84 FR 56391 (Oct. 22, 2019).
17 85 FR 10104 (Feb. 21, 2020).
18 85 FR 10104 (Feb. 21, 2020).
19 85 FR 19709 (Apr. 8, 2020).
20 84 FR 9051 (Mar. 13, 2019).
22 85 FR 31085 (May 22, 2020).
23 85 FR 55830 (Sept. 10, 2020).
26 85 FR 31085 (May 22, 2020).
Identity Theft Rules, which include the Red Flags Rule and the Card Issuer Rule. FTC staff is reviewing the comments received and anticipates sending a recommendation to the Commission by January 2022. The Red Flags Rule requires financial institutions and creditors to develop and implement a written identity theft prevention program (a Red Flags Program). By identifying red flags for identity theft in advance, businesses can be better equipped to spot suspicious patterns that may arise and take steps to prevent potential identity theft. The Commission initiated a costly episode of identity theft. The Card Issuer Rule requires credit and debit card issuers to implement reasonable policies and procedures to assess the validity of a change of address if they receive notification of a change of address for a consumer’s debit or credit card account and, within a short period of time afterwards, also receive a request for an additional or replacement card for the same account. The comment period closed on October 26, 2014. Staff anticipates making a recommendation to the Commission by November 2021.

b. Proposed Rules

Since the publication of the 2020 Regulatory Plan, the Commission has initiated or plans to take further steps as described below in the following rulemaking proceedings: Care Labeling Rule, 16 CFR 423. On July 23, 2020, the Commission issued a Supplemental Notice of Proposed Rulemaking seeking comment on a proposed repeal of the Rule. On July 21, 2021, the Commission voted to retain the Care Labeling Rule (officially the Rule on Care Labeling of Textile Apparel and Certain Piece Goods as Amended) to ensure American consumers continue to get accurate information on how to take care of their fabrics and extend the life of their clothes. In a public statement, the Commission also indicated that it would continue to consider ways to improve the Rule to the benefit of families and businesses. Promulgated in 1971, the Care Labeling Rule makes it an unfair or deceptive act or practice for manufacturers and importers of textile wearing apparel and certain piece goods to sell these items without attaching care labels stating what regular care is needed for the ordinary use of the product. The Rule also requires that the manufacturer or importer possess, prior to sale, a reasonable basis for the care instructions and allows the use of approved care symbols in lieu of words to disclose care instructions.

Energy Labeling Rule, 16 CFR 305. The Energy Labeling Rule requires energy labeling for major home appliances and other consumer products to help consumers compare the energy usage and costs of competing models. Staff anticipates sending the Commission a recommendation to update comparability ranges for 16 CFR 305.12 by April 2022. The Eyeglass Rule, 16 CFR 456. As part of the systematic review process, the Commission issued a Federal Register notice seeking public comments about the Trade Regulation Rule on Ophthalmic Practice Rules (Eyeglass Rule) on September 3, 2015. The comment period closed on October 26, 2015. Commission staff has completed the review of 831 comments on the Eyeglass Rule and anticipates sending a recommendation for further Commission action by November 2021. The Eyeglass Rule requires that an optometrist or ophthalmologist give the patient, at no extra cost, a copy of the eyeglass prescription immediately after the examination is completed. The Rule also prohibits optometrists and ophthalmologists from conditioning the availability of an eye examination, as defined by the Rule, on a requirement that the patient agree to purchase ophthalmic goods from the optometrist or ophthalmologist.

Safeguards Rule (Standards for Safeguarding Customer Information), 16 CFR 314. The FTC’s Safeguards Rule, which was issued under the Gramm-Leach-Bliley Act, requires each financial institution subject to the FTC’s jurisdiction to assess risks and develop a written information security program that is appropriate to its size and complexity, the nature and scope of its activities, and the sensitivity of the customer information at issue. On October 27, 2021, the Commission announced the issuance of a Supplemental Notice of Proposed Rulemaking that proposes to further amend the Safeguards Rule to require financial institutions to report to the Commission any security event where the financial institutions have determined misuse of customer information has occurred or is reasonably likely and that at least 1,000 consumers have been affected or reasonably may be affected. The comment period closes 60 days after publication in the Federal Register.

c. Final Actions

Since the publication of the 2020 Regulatory Plan, the Commission has issued the following final agency actions in rulemaking proceedings: Energy Labeling Rule, 16 CFR 305. On February 12, 2021, the Commission published a final rule that establishes EnergyGuide labels for portable air conditioners and requires manufacturers to label portable air conditioner units produced after October 1, 2022. The Commission also updated the Rule in conformity with new DoE energy descriptors for central air conditioner units that will become effective on January 1, 2023. Additionally, on October 20, 2021, the Commission issued a final rule updating the comparability ranges and sample labels.
for central air conditioners. The amendments are effective on January 1, 2023.

Fair Credit Reporting Act Rules, 16 CFR 640–642, 660, and 680. On September 8, 2021, the Commission announced final rules for each of these Rule reviews that included revisions to the Rules to correspond to changes to the Fair Credit Reporting Act made by the Dodd-Frank Act. The final rules were effective 30 days after publication in the Federal Register. These rules include: Duties of Creditors Regarding Risk-Based Pricing, 16 CFR 640; Duties of Users of Consumer Reports Regarding Address Discrepancies, 16 CFR 641; Prescreen Opt-Out Notice, 16 CFR 642; Duties of Furnishers of Information to Consumer Reporting Agencies, 16 CFR 660; and Affiliate Marketing, 16 CFR 680.

Made in USA Labeling Rule, 16 CFR 323. On July 14, 2021, the Commission issued a final rule that codified the FTC’s longstanding enforcement policy statement regarding U.S.-origin claims. The rule was effective on August 13, 2021. The Rule prohibits marketers from making unqualified MUSA claims on labels unless final assembly or processing of the product occurs in the United States; all significant processing that goes into the product occurs in the United States; and all or virtually all ingredients or components of the product are made and sourced in the United States. The rule does not impose any new requirements on businesses. By codifying this guidance into a formal rule, the Commission can increase deterrence of Made in USA fraud and seek restitution for victims. The final rule included a provision allowing marketers to seek exemptions if they have evidence showing their unqualified Made-in-USA claims are not deceptive.

Privacy of Consumer Financial Information Rule, 16 CFR 313. The Privacy of Consumer Financial Information Rule (Rule) requires, among other things, that certain motor vehicle dealers provide an annual disclosure of their privacy policies to their customers by hand delivery, mail, electronic delivery, or through a website, but only with the consent of the consumer. On October 27, 2021, the Commission announced the issuance of a final rule to, among other changes, revise the Rule’s scope, modify the Rule’s definitions of “financial institution” and “federal functional regulator,” and update the Rule’s annual customer privacy notice requirement. This action was necessary to conform the Rule to the current requirements of the Gramm-Leach-Bliley Act. The amendments will be effective 30 days after publication in the Federal Register.

The Prohibition of Energy Market Manipulation Rule, 16 CFR 317. On March 2, 2021, the Commission completed its regulatory review and issued a Federal Register Notice confirming that the Rule was being retained without modification.

Safeguards Rule (Standards for Safeguarding Customer Information), 16 CFR 314. The FTC’s Safeguards Rule, which was issued under the Gramm-Leach-Bliley Act, requires each financial institution subject to the FTC’s jurisdiction to assess risks and develop a written information security program that is appropriate to its size and complexity, the nature and scope of its activities, and the sensitivity of the customer information at issue. On October 27, 2021, the Commission announced the issuance of a final rule that, among other amendments, provides additional requirements for financial institutions’ information security programs. The final rule also expands the definition of “financial institution” to include entities that are significantly engaged in activities that are incidental to financial activities, so that the rules would cover “finders”—for example, companies that serve as lead generators for payday loan companies or mortgage companies. Certain provisions of the amendments, set forth in section 314.5 of the final rule, will be effective one year after the publication of the final rule in the Federal Register. The remainder of the amendments are effective 30 days after Federal Register publication.

d. Significant Regulatory Actions

The Commission has no proposed rule that would be a “significant regulatory action” under the definition in Executive Order 12866. The Commission also has no proposed rule that would have significant international impacts, or any international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations, as defined in Executive Order 13609.

Summary

The actions under consideration advance the Commission’s mission by informing and protecting consumers while minimizing burdens on honest businesses. The Commission continues to identify and weigh the costs and benefits of proposed regulatory actions and possible alternative actions.

BILLING CODE 6750–01–P

NATIONAL INDIAN GAMING COMMISSION (NIGC)

Statement of Regulatory Priorities

In 1988, Congress adopted the Indian Gaming Regulatory Act (IGRA) (Pub L. 100–497, 102 Stat. 2475) with a primary purpose of providing “a statutory basis for the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments.” IGRA established the National Indian Gaming Commission (NIGC or the Commission) to protect such gaming, amongst other things, as a means of generating tribal revenue for strengthening tribal governance and tribal communities.

At its core, Indian gaming is a function of sovereignty exercised by tribal governments. In addition, the Federal government maintains a government-to-government relationship with the tribes—a responsibility of the NIGC. Thus, while the Agency is committed to strengthening Indian gaming, the Commission is equally committed to strengthening government-to-government relations by engaging in meaningful consultation with tribes to fulfill IGRA’s intent. The NIGC’s vision is to adhere to principles of good government, including transparency to promote agency accountability and fiscal responsibility, to operate consistently to ensure fairness and clarity in the administration of IGRA, and to respect the responsibilities of each sovereign in order to fully promote tribal economic development, self-sufficiency, a strong workforce, and strong tribal governments.
Retrospective Review of Existing Regulations

As an independent regulatory agency, the NIGC has been performing a retrospective review of its existing regulations. The NIGC recognizes the importance of Executive Order 13563, issued on January 18, 2011, and its regulatory review is being conducted in the spirit of Executive Order 13563, to identify those regulations that may be outdated, ineffective, insufficient, or excessively burdensome and to modify, streamline, expand, or repeal them in accordance with input from the public. In addition, as required by Executive Order 13175, issued on November 6, 2000, the Commission has been conducting government-to-government consultations with tribes regarding each regulation’s relevancy, consistency in application, and limitations or barriers to implementation, based on the tribes’ experiences. The consultation process is also intended to result in the identification of areas for improvement and needed amendments, if any, new regulations, and the possible repeal of outdated regulations.

The following Regulatory Identifier Numbers (RINs) have been identified as associated with the review:

<table>
<thead>
<tr>
<th>RIN</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>3141–AA32</td>
<td>Definitions.</td>
</tr>
<tr>
<td>3141–AA70</td>
<td>Class II Minimum Internal Control Standards.</td>
</tr>
<tr>
<td>3141–AA58</td>
<td>Management Contracts.</td>
</tr>
<tr>
<td>3141–AA69</td>
<td>Class II Minimum Technical Standards.</td>
</tr>
<tr>
<td>3141–AA71</td>
<td>Background and Licensing.</td>
</tr>
<tr>
<td>3141–AA68</td>
<td>Audit Regulations.</td>
</tr>
<tr>
<td>3141–AA72</td>
<td>Self-Regulation of Gaming Activities.</td>
</tr>
<tr>
<td>3141–AA73</td>
<td>Gaming Ordinance Submission Requirements.</td>
</tr>
<tr>
<td>3141–AA74</td>
<td>Substantial Violations List.</td>
</tr>
<tr>
<td>3141–AA75</td>
<td>Appeals to Commission.</td>
</tr>
<tr>
<td>3141–AA76</td>
<td>Facility License Notifications and Submissions.</td>
</tr>
<tr>
<td>3141–AA77</td>
<td>Fees.</td>
</tr>
<tr>
<td>3141–AA79</td>
<td>Suspensions of Gaming Licenses for Key Employees and Primary Management Officials.</td>
</tr>
<tr>
<td>3141–AA80</td>
<td>Fee Rate Assessment, Reporting, and Calculation Guidelines for Self Regulated Tribes.</td>
</tr>
<tr>
<td>3141–AA81</td>
<td>Orders of Temporary Closure.</td>
</tr>
</tbody>
</table>

More specifically, the NIGC is currently considering promulgating new regulations in the following areas: (i) Amendments to its regulatory definitions to conform to the newly-promulgated rules; (ii) updates or revisions to its management contract regulations to address the current state of the industry; (iii) updates or revisions to the existing audit regulations to reduce cost burdens for small or charitable gaming operations; (iv) the review and revision of the minimum technical standards for Class II gaming; (v) the review and revision of the minimum internal control standards (MICS) for Class II gaming; (vi) background and licensing; (vii) self-regulation of Class II gaming activities; (viii) gaming ordinance submission requirements; (ix) substantial violations; (x) appeals to the Commission; (xi) facility license notification and submission; (xii) fees; (xiii) updating its regulations concerning suspension of licenses issued to Key Employees and Primary Management Officials who the NIGC determines are not eligible for employment; (xiv) amending its regulations concerning fee rate assessment, carry over status reporting process, budget commitments for maintaining transition funds, and fee rate calculation guidelines for self-regulated tribes; (xv) amending a substantial violations identified in its regulations to provide that closure for a tribe’s failure to construct and operate its gaming operation in a manner that adequately protects the environment, public health, and safety includes issues related to cyber-security.

The NIGC is committed to staying up-to-date on developments in the gaming industry, including best practices and emerging technologies. Further, the Commission aims to continue reviewing its regulations to determine whether they are overly burdensome to tribes and industry stakeholders, including smaller or rural operations. The NIGC anticipates that the ongoing consultations with tribes will continue to play an important role in the development of the NIGC’s rulemaking efforts.

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U.S. NUCLEAR REGULATORY COMMISSION

Statement of Regulatory Priorities for Fiscal Year 2022

I. Introduction

Under the authority of the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, the U.S. Nuclear Regulatory Commission (NRC) regulates the possession and use of source, byproduct, and special nuclear material. Our regulatory mission is to license and regulate the Nation’s civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety and promote the common defense and security. As part of our mission, we regulate the operation of nuclear power plants and fuel-cycle plants; the safeguarding of nuclear materials from theft and sabotage; the safe transport, storage, and disposal of radioactive materials and wastes; the decommissioning and safe release for other uses of licensed facilities that are no longer in operation; and the medical, industrial, and research applications of nuclear material. In addition, we license the import and export of radioactive materials.

As part of our regulatory process, we routinely conduct comprehensive regulatory analyses that examine the costs and benefits of contemplated regulations. We have developed internal procedures and programs to ensure that we impose only necessary requirements on our licensees and to review existing regulations to determine whether the requirements imposed are still necessary.

Our regulatory priorities for fiscal year (FY) 2022 reflect our safety and security mission and will enable us to achieve our two strategic goals described in NUREG–1614, Volume 7, “Strategic Plan: Fiscal Years 2018–2022” (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v7/) (1) to ensure the safe use of radioactive materials, and (2) to ensure the secure use of radioactive materials.
II. Regulatory Priorities

This section contains information on some of our most important and significant regulatory actions that we are considering issuing in proposed or final form during FY 2022. The NRC’s high-priority rulemaking titled “Risk-Informed, Technology Inclusive Regulatory Framework for Advanced Reactors (RIN 3150–AK31; NRC–2019–0062)” is not included in this report due to the timeframe for reporting, as the agency will not be publishing it in proposed or final form during FY 2022. The proposed rule is expected to be published in FY 2023. For additional information on NRC rulemaking activities and on a broader spectrum of our upcoming regulatory actions, see our portion of the Unified Agenda of Regulatory and Deregulatory Actions. We also provide additional information on planned rulemaking and petition for rulemaking activities, including priority and schedule, on our website at https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html.

A. NRC’s Priority Rulemakings

Proposed Rules

Advanced Nuclear Reactor Generic Environmental Impact Statement (RIN 3150–AK55; NRC–2020–0101): This rule would amend the regulations that govern the NRC’s environmental reviews under National Environmental Policy Act (NEPA) by codifying the findings of the advanced nuclear reactor generic environmental impact statement.

Alternative Physical Security Requirements for Advanced Reactors (RIN 3150–AK19; NRC–2017–0227): This rule would amend the NRC’s physical security requirements for small modular reactors and other advanced reactor technologies.

Cyber Security for Fuel Facilities (RIN 3150–AJ64; NRC–2015–0179): This rule would amend the NRC’s regulations to add cyber security requirements for certain nuclear fuel cycle facility applicants and licensees.

Final Rules


Emergency Preparedness Requirements for Small Modular Reactors and Other New Technologies (RIN 3150–AJ68; NRC–2015–0225): This rule will amend the regulations to add new emergency preparedness requirements for small modular reactors and other new technologies such as non-light-water reactors and non-power production or utilization facilities.

NuScale Small Modular Reactor Design Certification (RIN 3150–AJ98; NRC–2017–0029): This rulemaking will amend the NRC’s regulations to incorporate the NuScale small modular reactor standard plant design.

B. Significant Final Rules

The following rulemaking activity meets the requirements of a significant regulatory action in Executive Order 12866, “Regulatory Planning and Review,” because it is likely to have an annual effect on the economy of $100 million or more.

Revision of Fee Schedules: Fee Recovery for FY 2022 (RIN 3150–AK44; NRC–2020–0031): This rule will amend the NRC’s fee schedules for licensing, inspection, and annual fees charged to its applicants and licensees.

NRC

Proposed Rule Stage


Priority: Other Significant.

Legal Authority: 42 U.S.C. 2201; 42 U.S.C. 5841

CFR Citation: 10 CFR 40; 10 CFR 70; 10 CFR 73.

Legal Deadline: None.

Abstract: This rulemaking would amend the NRC’s regulations to add cyber security requirements for certain nuclear fuel cycle facility applicants and licensees. The rule would require certain fuel cycle facilities to establish, implement, and maintain a cyber security program that is designed to protect public health and safety and the common defense and security. It would affect fuel cycle applicants or licensees that are or plan to be authorized to: (1) Possess greater than a critical mass of special nuclear material and perform activities for which the NRC requires an integrated safety analysis or (2) engage in uranium hexafluoride conversion or deconversion.

Statement of Need: The NRC currently does not have a comprehensive regulatory framework for addressing cyber security at fuel cycle facilities (FCFs). Each FCF licensee is subject to either design basis threats (DBTs) or to the Interim Compensatory Measures (ICM) Orders issued to all FCF licensees subsequent to the events of September 11, 2001. Both the DBTs and the ICM Orders contain a provision that these licensees include consideration of a cyber attack when considering security vulnerabilities. However, the NRC’s current regulations do not provide specific requirements or guidance on how to implement these performance objectives. Since the issuance of the ICM Orders and the 2007 DBT rulemaking, the threats to digital assets have increased both globally and nationally. Cyber attacks have increased in number, become more sophisticated, resulted in physical consequences, and targeted digital assets similar to those used by FCF licensees. The rulemaking would establish requirements for FCF licensees to establish, implement, and maintain a cyber security program to detect, protect against, and respond to a cyber attack capable of causing a consequence of concern. The design of this cyber security program would provide flexibility to account for the various types of FCFs, promote common defense and security, and provide reasonable assurance that the public health and safety remain adequately protected against the evolving risk of cyber attacks.


Alternatives: As an alternative to the rulemaking, the NRC staff considered the “no-action” alternative. Under this option the NRC would not modify 10 CFR part 73. The NRC considered a number of additional approaches to improving cyber security at FCFs, including issuing generic communications, developing new guidance documents, and revising existing inspection modules or enforcement guidance. Because these approaches would not fully address the regulatory issues, the NRC did not evaluate them as alternatives to the proposed action. Because the Commission had previously rejected the issuance of orders to resolve these regulatory issues, orders were not evaluated as an alternative for this rulemaking.

Anticipated Cost and Benefits: The NRC evaluated the provisions of the proposed rule in the Regulatory Basis and concluded that the provisions provide a substantial increase in the overall protection of public health and safety through effective implementation of the cyber security program to prevent safety consequences of concern. The analysis further demonstrated that the costs for the proposed rule provisions are cost justified for the additional protection provided.

Risks: In the absence of specific NRC requirements, FCF licensees have...
implemented limited, ad hoc, voluntary cyber security measures. Voluntary cyber security measures do not include a complete set of controls for digital assets, which leaves facilities susceptible to potential vulnerabilities and the programs may not be enforceable unless licensees incorporate them into their licensing basis. This may result in a cyber security program that is unable to adequately address the evolving cyber security threat confronting FCF licensees.

**Timetable:**

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<th>Action</th>
<th>Date</th>
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<td>80 FR 53478</td>
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<td>10/05/15</td>
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<tr>
<td>Final Regulatory Basis</td>
<td>04/12/16</td>
<td>81 FR 21449</td>
</tr>
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<td>12/00/21</td>
<td></td>
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<tr>
<td>Final Rule ..........</td>
<td>10/00/22</td>
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</tr>
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</table>

**Regulatory Flexibility Analysis**

**Required:** No.

**Small Entities Affected:** No.

**Government Levels Affected:** None.

**Additional Information:** The proposed rule was provided to the Commission on October 4, 2017 (SECY–17–0099), (ADAMS Package Accession No. ML17018A218).

**Agency Contact:** Irene Wu, Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555–0001, Phone: 301 415–1951, Email: irene.wu@nrc.gov. RIN: 3150–AJ64

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### NRC


**Priority:** Other Significant.

**Legal Authority:** 42 U.S.C. 2201; 42 U.S.C. 5841

**CFR Citation:** 10 CFR 73

**Legal Deadline:** None.

**Abstract:** This rule would amend the NRC’s physical security requirements for small modular reactors and other advanced reactor technologies. This rulemaking would establish voluntary alternative physical security requirements commensurate with the potential consequences to public health and safety and the common defense and security. This rulemaking would provide regulatory stability, predictability, and clarity in the licensing process and minimize or eliminate uncertainty for applicants who might otherwise request exemptions from the regulations.

**Statement of Need:** Required by NEIMA.

**Summary of Legal Basis:** Policy Statement on the Regulation of Advanced Reactors, published in the Federal Register (FR) on October 14, 2008 (73 FR 60612). Staff Requirements Memorandum (SRM)-SECY–18–0076, dated November 19, 2018, (ADAMS Accession No. ML18324A478), the Commission approved the staff’s recommendation to initiate a limited-scope rulemaking.

**Alternatives:** SECY–18–0076, Options and Recommendation for Physical Security for Advanced Reactors, dated August 1, 2018, (ADAMS Accession No. ML18170A051), presenting alternatives and a recommendation to the Commission on possible changes to the regulations and guidance related to physical security for advanced reactors (light-water small modular reactors and non-light-water reactors). The staff evaluated the advantages and disadvantages of each alternative and recommended a limited-scope rulemaking to further assess and, if appropriate, revise a limited set of NRC regulations. The staff also recommended developing necessary guidance to address performance criteria for which the alternative requirements may be applied for advanced reactor license applicants.

**Anticipated Cost and Benefits:** The estimated benefits of the proposed action include (1) fewer exemption requests as compared to those made under current regulations, (2) fewer security staff or other security features compared to those currently required by 10 CFR 73.55 commensurate with offsite consequences and radiation risks to public health and safety, (3) consistent regulatory applicability in the review of physical security plans in accordance with 10 CFR part 73, and (4) potential use of a more risk-informed, performance-based physical security framework.

**Risks:** None.

**Timetable:**

<table>
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<th>Action</th>
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<td>84 FR 33861</td>
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<td>12/00/21</td>
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</table>

**Regulatory Flexibility Analysis**

**Required:** No.

**Small Entities Affected:** No.

**Government Levels Affected:** None.

**Additional Information:** NRC is not issuing a final regulatory basis and will address comments on the regulatory basis (84 FR 33861) in the proposed rule.

**Agency Contact:** Dennis Andrukat, Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555–0001, Phone: 301 415–3561, Email: dennis.andrukat@nrc.gov. RIN: 3150–AK19

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**NRC**

#### 177. Revision of Fee Schedules: Fee Recovery for FY 2022 [NRC–2020–0031]

**Priority:** Economically Significant. Major under 5 U.S.C. 601.


**CFR Citation:** 10 CFR 170; 10 CFR 171.

**Legal Deadline:** NPRM, Statutory, September 30, 2022.

The Nuclear Energy Innovation and Modernization Act (NEIMA) requires the NRC to assess and collect service fees and annual fees in a manner that ensures that, to the maximum extent practicable, the amount assessed and collected approximates the NRC’s total budget authority for that fiscal year less the NRC’s budget authority for excluded activities. NEIMA requires that the fees for FY 2022 be collected by September 30, 2022.

**Abstract:** This rulemaking would amend the NRC’s regulations for fee schedules. The NRC conducts this rulemaking annually to recover approximately 100 percent of the NRC’s FY 2022 budget authority, less excluded activities to implement NEIMA. This rulemaking would affect the fee schedules for licensing, inspection, and annual fees charged to the NRC’s applicants and licensees.

**Statement of Need:** The NRC, as required by statute conducts an annual rulemaking in order to assess and collect service fees and annual fees in a manner that ensures that, to the maximum extent practicable, the amount assessed and collected approximates the NRC’s total budget authority for that fiscal year less the NRC’s budget authority for excluded activities. NEIMA requires the NRC to establish through rulemaking a schedule of annual fees that fairly and equitably allocates the aggregate amount of annual fees among licensees and certificate holders. NEIMA states that this schedule may be based on the allocation of the NRC’s resources among licensees, certificate holders, or classes of licensees or certificate holders and requires that the schedule of annual fees, to the maximum extent practicable, shall be reasonably related to the cost of providing regulatory services.
Summary of Legal Basis: Effective October 1, 2020, NEIMA puts in place a revised framework for fee recovery by eliminating OBRA–90’s approximately 90 percent fee-recovery requirement and requiring the NRC to assess and collect service fees and annual fees in a manner that ensures that, to the maximum extent practicable, the amount assessed and collected approximates the NRC’s total budget authority for that fiscal year less the NRC’s budget authority for excluded activities.

Alternatives: Because this action is mandated by statute and the fees must be assessed through rulemaking, the NRC did not consider alternatives to this action.

Anticipated Cost and Benefits: The cost to the NRC’s licensees is approximately 100 percent of the NRC FY 2022 budget authority less the amounts appropriated for excluded activities.

Risks: None.

NRC


Priority: Other Significant.
Legal Authority: 42 U.S.C. 2201; 42 U.S.C. 5841
CFR Citation: 10 CFR 50; 10 CFR 52.
Legal Deadline: None.
Abstract: This rulemaking would amend the NRC’s regulations to add new emergency preparedness requirements for small modular reactors and other new technologies such as non-light-water reactors and non-power production or utilization facilities. The rule would adopt a scalable plume exposure pathway emergency planning zone approach that is performance-based, consequence-oriented, and technology-inclusive. This rulemaking would affect applicants for new NRC licenses and reduce regulatory burden related to the exemption process.

Statement of Need: Current emergency preparedness (EP) regulations do not sufficiently reflect the advances in designs and more recent safety research, particularly with respect to small modular reactors (SMRs) and other new technologies (ONTs), such as non-light-water reactors (non-LWRs) and medical isotope facilities.

Summary of Legal Basis: None.

Alternatives: None.

Anticipated Cost and Benefits: The proposed rule would be projected to result in a cost-justified change based on a net (i.e., accounting for both costs and benefits) averted cost to the industry that ranges from $4.72 million using a 7-percent discount rate to $7.56 million using a 3-percent discount rate. Relative to the regulatory baseline, the NRC would realize a net averted cost of $1.17 million using a 7-percent discount rate and $2.16 million using a 3-percent discount rate. The proposed rule alternative would result in net averted costs to the industry and the NRC ranging from $5.89 million using a 7-percent discount rate to $9.71 million using a 3-percent discount rate. 

Risks: None.

NRC


Priority: Other Significant.
Legal Authority: 42 U.S.C. 2201; 42 U.S.C. 5841
CFR Citation: 10 CFR 50.
Legal Deadline: None.
Abstract: This rulemaking would amend the NRC’s regulations that govern the agency’s National Environmental Policy Act (NEPA) reviews. The rulemaking would codify the findings of the Advanced Nuclear Reactor Generic Environmental Impact Statement (ANR GEIS). The ANR GEIS would use a technology-neutral regulatory framework and performance-based assumptions to determine generic environmental impacts for new commercial advanced nuclear reactors. The ANR GEIS would streamline the NEPA reviews for future advanced reactor applicants.

Statement of Need: The NRC is developing a GEIS for advanced nuclear reactors in order to streamline the environmental review process for future advanced nuclear reactor (ANR) environmental reviews. The purpose of an ANR GEIS is to determine which environmental impacts would result in essentially the same (generic) impact for different ANR designs that fit within the parameters set in the GEIS, and which environmental impacts would require a plant-specific analysis. Environmental reviews for advanced nuclear reactor license applications could incorporate the ANR GEIS by reference and provide site-specific information and analyses in a Supplemental Environmental Impact Statement (SEIS), thereby streamlining the environmental review process.


Alternatives: As an alternative to the rulemaking, the NRC staff considered the ‘no-action’ alternative. Under this alternative the NRC would not modify 10 CFR part 51 to codify the results of the ANR GEIS. This alternative would not provide the benefits of streamlining the environmental review process. Therefore, rulemaking is the preferred alternative.

Anticipated Cost and Benefits: The anticipated benefits would exceed the costs associated with the proposed regulatory action. The supporting regulatory analysis will provide a detailed analysis of the costs and benefits associated with this action.

Risks: None.

NRC


Priority: Other Significant.
Legal Authority: 42 U.S.C. 2201; 42 U.S.C. 5841
CFR Citation: 10 CFR 50; 10 CFR 52.
Legal Deadline: None.
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Summary of Legal Basis: None.

Alternatives: None.

Anticipated Cost and Benefits: The proposed rule would be projected to result in a cost-justified change based on a net (i.e., accounting for both costs and benefits) averted cost to the industry that ranges from $4.72 million using a 7-percent discount rate to $7.56 million using a 3-percent discount rate. Relative to the regulatory baseline, the NRC would realize a net averted cost of $1.17 million using a 7-percent discount rate and $2.16 million using a 3-percent discount rate. The proposed rule alternative would result in net averted costs to the industry and the NRC ranging from $5.89 million using a 7-percent discount rate to $9.71 million using a 3-percent discount rate.

Risks: None.

Priority: Other Significant.
Legal Authority: 42 U.S.C. 2201; 42 U.S.C. 5841
CFR Citation: 10 CFR 52.
Legal Deadline: None.
Abstract: This rulemaking would amend the NRC’s regulations to incorporate the NuScale small modular reactor (SMR) standard plant design. The rulemaking would add a new appendix for the initial certification of the NuScale SMR standard plant design. This action would allow applicants intending to construct and operate an SMR to reference this design certification rule in future applications.

Statement of Need: This rule would place the NuScale standard design certification, once issued by the Commission, into the Code of Federal Regulations (CFR).

Summary of Legal Basis: The regulations in 10 CFR 52.51 require the NRC to initiate rulemaking after an application is filed under 10 CFR 52.45.

Alternatives: Based on a review of NuScale Power’s evaluation, the NRC concludes that: (1) NuScale Power identified a reasonably complete set of potential design alternatives to prevent and mitigate severe accidents for the NuScale design and (2) none of the potential design alternatives appropriate at the design certification stage are justified on the basis of cost/benefit considerations.

Anticipated Cost and Benefits: There is no anticipated increase in costs for consumers, individual industries, or geographical regions as a result of the rulemaking. This action will certify a reactor design; it does not constitute the license for construction of a nuclear power plant at a site.

Risks: None.

Timetable:

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Priority: Other Significant.
Legal Authority: 42 U.S.C. 2201; 42 U.S.C. 5841
CFR Citation: 10 CFR 50.
Legal Deadline: None.
Abstract: This rulemaking would amend the NRC’s regulations to authorize the use of recent editions of American Society of Mechanical Engineers (ASME) codes. The rule would incorporate by reference the 2019 Edition of the ASME Boiler and Pressure Vessel Code and the 2020 Edition of the ASME Operations and Maintenance of Nuclear Power Plants Code into the NRC’s regulations, with conditions. This action increases consistency across the industry and makes use of current voluntary consensus standards (as required by the National Technology Transfer and Advancement Act), while continuing to provide adequate protection to the public. This rulemaking would affect nuclear power reactor licensees.

Statement of Need: The need for the rulemaking is to update the regulations to incorporate the latest editions of consensus standards.

Anticipated Cost and Benefits: There is no anticipated cost change based on a net (i.e., taking into account both costs and benefits) averted cost to the industry ranging from $6.26 million (7-percent net present value (NPV)) to $6.99 million (3-percent NPV). Relative to the regulatory baseline, the NRC would realize a net averted cost ranging from $0.49 million (7-percent NPV) to $0.57 million (3-percent NPV). The total costs and benefits of proceeding with the rule would result in net averted costs to the industry and the NRC ranging from $6.75 million (7-percent NPV) to $7.56 million (3-percent NPV). Other benefits of the proposed rule include the NRC’s continued ability to meet its goal of ensuring the protection of public health and safety and the environment through the agency’s approval of new editions of the ASME BPV Code and ASME OM Code, which allow the use of the most current methods and technology.

Risks: In the absence of incorporation by the reference of the latest Editions of ASME Codes, licensees will continue to implement Code editions that are currently incorporated by reference in the rule and will not be able to take advantage of the latest advantages of ASME Codes, including relaxation of
certain requirements in the proposed rule. Thus, licensees will have to continue to implement the requirements of older Code editions and continue to request exemptions from certain requirements that would otherwise not be needed. This may result in nuclear power plant licensees, who would be the primary beneficiaries, to not be able to apply the latest editions of ASME Codes, and the NRC would not be able to meet its goal of ensuring the protection of public health and safety and the environment by continuing to provide the NRC’s approval of ASME Code editions that allow the use of the most current methods and technology and that may decrease the likelihood of an accident and, therefore, decrease the overall risk to public health.

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